69

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April 13, 2005

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
File Code: CMS-3818-P
PO Box 8012
Baltimore, MD 21244-8012

Dear Dr. McClellan:

I am writing to offer comments regarding the proposed revisions to the Conditions for Coverage for End Stage Renal Disease Facilities. Specifically I wish to comment on Proposed § 494.140 as this section addresses the possible role of a pharmacist within the dialysis facility. I appreciate that the Proposed Rule acknowledges the well-documented contributions a pharmacist can make to the safe and effective use of medications in vulnerable dialysis patient population.

As an Ambulatory Care Pharmacist presently I have the opportunity to monitor patient's Warfarin levels, pain management, diabetes and hypertension bringing patients to goal. Presently, I have several dialysis patient who generally utilize a greater amount of medications and run a higher risk of drug interactions and complications. Drug monitoring and therapy review would provide a valuable and potentially important service in reducing drug costs and medical error prevention.

I believe that consultant pharmacists should be included as part of the dialysis facility staff for the following reasons:

- the complex nature of drug therapy in dialysis patients,
- the pharmacokinetic complexity of drugs during dialysis
- the vulnerability of these patients for adverse medication-related outcomes,
- the need for storage, preparation, and administration of medications within the dialysis unit,
- the need for cost effective drug therapy,
- the changing nature of drug therapy that will arise due to the MMA, and
- the training of pharmacists that prepares them to serve as consultants to dialysis facilities.

Specifically, I would like to make the following recommendations:

1. The multidisciplinary dialysis team should include a consultant pharmacist with experience or training in nephrology pharmacy.
2. The routine patient care assessment of dialysis patients should include a medication review by a pharmacist.
3. Medication reviews should be conducted at least monthly. This frequency is consistent with what is required in skilled nursing and intermediate care facilities.
4. Pharmacists should participate in the development and implementation of medication-related protocols within dialysis centers to assure cost-effective drug use.
5. Dialysis facilities should develop and maintain appropriate policies for the safe storage, preparation and administration of medications within the facility. These policies should be developed and maintained in consultation with a pharmacist.]

Thank you for the opportunity to discuss this matter with caring health care professionals.

Charles Bonanno, PharmD., MBA, CGP

Centers for Medicare and Medicaid Services
Attention: CMS-3818-P
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April 20, 2005

I am responding to the proposed CMS Conditions of Coverage for dialysis facilities (CMS-3818-P). I will respond to several sections of the proposed regulations, using the issue identifier number that precedes the sections I am responding to.

Please note that I have been a nephrology social worker for over 21 years. I have also been in the forefront of responding to the changing needs of the health care environment. I supervise 15 MSW's that serve over 1500 dialysis patients and their families in the greater San Diego area. I have worked hard the past eight years to design nephrology social work interventions that both improve patient treatment outcomes (adherence, quality of life, rehabilitation) and reduce ESRD program costs (as it is stated in both lost revenue for the dialysis clinic and hospitalization costs for the federal government). I co-authored the National Kidney Foundation CNSW Outcomes Training Program to help nephrology social workers nationwide to move toward a similar disease management model of professional practice. I have seen every barrier to making this happen that exists, and have overcome the majority of them. It is from this vantage point that I offer my calculated comments.

6187-2494 Subpart C-Patient Care

6202-2 494.70(b) Patients Rights

I believe that the wording in this section could be strengthened by saying that all standards in the industry should be deployed to reduce the patients potential for continued disruption prior to discharge of a patient. This would include: engaging in genuine, professional exploration with the patient re his/her concerns, psycho-social in-service education of the renal team re complex pt. behavior, pt.-administrator problem-solving meetings, behavioral contracts, the use of mediation and even suspension with medical evaluation and treatment until the patient's behavior can be stabilized. (Here is my article which focuses on this issue: *Johnstone S, Seamon VJ, Halshaw D, Molinari J, and Longknife K. "The use of mediation to manage patient-staff conflict in the dialysis clinic." Advances in Renal Replacement Therapy 4(4) 1997; 359-371.*) Discharge should be the last resort since it is nearly impossible for a discharged patient to gain entry into another outpatient dialysis facility in the current "resistant" and "avoidant" management environment. This is even more important, in my opinion, since I frequently see tired renal team members vote to discharge a patient upon the first incident, or for a small incident that is not "dangerous" for fear they just wont have the time to provide for any extra patient needs or just don't "like" a patient. The

management team often feels pressure from the treatment team to discharge. This dynamic is on the rise in the outpatient dialysis facility.

6208-3, 6208-1)
494.80(a)- (6249-2) I support the specifics you define "must" be included in the comprehensive assessment. I would add to the items required to be included in this assessment a # (14) : "evaluation of emotional and social rehabilitation needs". The literature suggests that these areas need rehabilitation focus also.

Kimmel, P. (2000). Psychosocial factors in adult end-stage renal disease patients treated with hemodialysis: correlates and outcomes. American Journal of Kidney Diseases, 35(Suppl), 132-140. ;

Husebye, D. G., Westle, L., Styrvoky, T. J. & Kjellstrand, C. M. (1987). Psychological, social, and somatic prognostic indicators in old patients undergoing long-term dialysis. Archives of Internal Medicine, 147, 1921-1924.

Callahan, MB, LeSage L, Johnstone, S. "A model for patient participation in quality of life measurement to improve patient rehabilitation outcomes". Nephrology News and Issues, 1999, 13 (1): 33-34;37.

Guzman SJ, Nicassio PM: The contribution of negative and positive illness schemas to depression in patients with end-stage renal disease. J Behav Med. 2003 Dec;26(6):517-34.

Lowrie EG, Curtin RB, Lepain N, Schatell,D: Medical outcomes study short form-36: A consistent and powerful predictor of morbidity and mortality in dialysis patients. American Journal of Kidney Diseases ; 41 (6,) 2003.

This section on assessment must call for something more specific than "evaluation of psychosocial needs, which focuses also on financial, environmental, caregiving concerns, etc. I would include "evaluation of emotional and social rehabilitation needs" either additionally, or combine it with # 7 evaluation of psychosocial needs to read "evaluation of psychosocial needs and areas for emotional/social rehabilitation.

494.80(b) (1) Patient Assessment
Regarding the proposed 20 calendar days to complete the "initial assessment"... I believe it is important to see this 20-day assessment as an early phase assessment of immediate needs and treatment outcome barriers. Our patients are increasingly admitted older and sicker, and are discharged to the outpatient dialysis clinic less than medically stable, they are often not prepared to engage in a full-team or more comprehensive evaluation. They are, however, at the 20-day mark, usually capable of participating in a brief screening of important care concerns and treatment barriers. I would recommend this 20-day initial assessment be presented as an initial screening of barriers and needs and be presented/titled in that way. Tools should be required to be developed appropriate to this task.

494.80(b)(2) I agree that the full comprehensive assessment should then be performed at the 90 day mark. I agree that this is a good time to begin to see a

patient at baseline and evaluate the patient in his/her more normal environment in order to, along with the patient, establish the most effective treatment plan.

494.80(d) It appears in this section you have removed the need for the social worker to reassess the patient quarterly. I am concerned about this—I am concerned that if stable patients are waiting a year between Social Work assessments, that their needs will be overlooked. In my experience, the patient assessment is helpful to getting the patient to identify and disclose underlying psychosocial problems. The social worker is not in regular contact with the patient as the nursing team or dietician is. In light of this, I would recommend that the social work re-assessment be done twice a year. (bi-annually)

(6205-1)
494.90 Condition: Patient Plan of Care
I support that the patients plan of care must include measurable and expected outcomes and estimated timetables. I would add that any delay in the pt. not meeting expected outcomes must be evaluated as to why, and that this formal evaluation of the process be documented and explained so that the state inspector could see that reasonable effort was made on behalf of the interdisciplinary team. I am deeply concerned that care plans are often being completed with little attention to expected outcome, and more attention to pacifying the potential state inspector. I am also concerned that the designed care plans are not being explained to patients in a way that they are able to participate in them or understand prior to them being asked to sign the plan. Often, rather than ask questions and appear to "need too much time from the team" the pt. often simply signs the plan and remain uninvolved.

494.90(a) Standard: Development of the patient care plan
I frequently hear that dialysis teams are not meeting in a group format in order to accomplish care planning. And I almost always hear that the physician is not present. I think language requiring that the team discuss the patient together is needed, and that each clinic must create a formal care planning environment and period of time to focus as in interdisciplinary team on each patient's needs.

494.90(a)(6)
I fully support the new focus on rehabilitation in the proposed regulation. I think the fact that the scope of rehabilitation is more defined by the regulations is important. Though there is effort to not regulate activities in these proposals, it is important to give guidance to the outpatient dialysis personnel in this area. In fact, I think further language should be added that necessitates the patient's full participation in rehabilitation and goal setting. I would remove the words "as desired by the patient" since those words make it too easy for the team to say "the patient was not interested in rehabilitation", when truthfully depression and lack of understanding what we are asking are the greatest barriers to this task. I would add language to the

effect that the team must make every effort to help a patient establish a small goal for improvement and that the patient must actively participate in the review and revision of the rehabilitation plan on an annual basis. In a study conducted by myself and several colleagues, we were taken by how much small goal-setting and reaching goals helped the patient improve.

Callahan, MB, LeSage L, Johnstone, S. "A model for patient participation in quality of life measurement to improve patient rehabilitation outcomes". Nephrology News and Issues, 1999, 13 (1): 33-34;37.

The dialysis patient's interest in rehabilitation is VERY easy to overlook by the busy renal team with few skills to address it. They must be approached from an individual level and asked questions like: what would you like to see different in 6 months in these areas: emotionally, socially, physically, vocationally, sexually, etc.) I also think bi-annual or quarterly evaluation of the plan is critical. An annual evaluation of rehabilitation progress is hardly enough. I also think the language in this section should call for a "comprehensive" rehabilitation program to be designed and operated by the clinic, and it should have performance measures established and reviewed by the interdisciplinary team. Finally, I would add emotional and social rehabilitation to the language (in addition to physical fitness, employment, activities, etc) to include these elements as they impact wellness and survival.

494.90(c) Standard: Transplantation Referral Tracking

I support the elimination of the "designee" status. It has been cumbersome to have the transplant centers sign the pt. care plan and it has been cumbersome to make sure each clinic has an MD willing to serve as designee. I like this proposed situation in that it puts the pressure on the renal team to communicate quarterly with the transplant team re patient status, including ensuring timely initial evaluation.

494.90(d) Standard: Patient Education and Training

I support this focus on patient education as part of the patient plan of care. It is **VERY** important that you have required it for the patient AND the family members/ or caregivers. I would strengthen the language of the proposal to say "each center must design educational tools (i.e. teaching sheets, videos, audios, etc) in these noted areas (you have effectively defined them as aspects of dialysis, dialysis mgmt, quality of life, rehabilitation and transplantation) and offer them to each patient/family and **have the patient/family sign that they have received this education.** If this further regulatory language is not offered, it will be too easy for the team to say "he wasn't interested" . My experience is that the pt is always interested, but we must find ways to bridge cognitive, mood and language barriers to help the pt. receive at least a minimal amount of education. A recent study that I did with colleagues showed that the education process should never end (see cite below). Follow-up education should be provided to ensure a patient's comprehension.

Johnstone S, Walrath L, Wohlwend V and Thompson C: *Overcoming early learning barriers in hemodialysis patients: the use of screening and educational reinforcement to improve treatment outcomes.* Advances in Chronic Kidney Disease April 2004 ,(11) 2, 210-216.

The quality assessment and performance improvement program that you propose would charge each dialysis facility with the responsibility for carrying out a performance improvement program of its own design, I believe, would need outcome thresholds pre-determined via the networks on an ongoing basis with state surveillance of facility dedication to this task. It has been my experience that with the internal pressures of dialysis facility operations, that these projects (even among the most well-meaning of administrators and medical directors) are often cut and pasted together quickly, and their interventions cut corners just to satisfy an inspector. It is far too easy to not to put effort into this task and still look progressive. I recommend that the facility be required to be prepared to keep a log/documentation of and display all reasonable efforts to improve.

(6208-3)
494.90 Patient Plan of Care
In this section you have effectively addressed the complex psycho-social-emotional-environmental-relational aspects of overall patient adjustment to illness that often serve as barriers to effective treatment outcomes. *You have requested suggestions for how to assess the multitude of psychosocial factors that can serve as barriers to effective patient outcomes.* I would recommend language in the regulations that the care plan for psychosocial services should include all the categories listed below that are of relevance to the patient. The categories addressed in the care plan should be reviewed with the patient to ensure we have included and addressed all current psycho-social barriers to pt. outcomes.

Concerns about
___mood (depression/anxiety/anger/suicide ideation)
___financial status
___insurance status
___employment status
___relationship with spouse, partner or family
___concerns re sexual functioning
___concerns re changes in cognitive status
___concerns re adherence to treatment regime
___changes In roles/Social functioning
___satisfaction with care at the clinic

Once the applicable problems listed above are identified, interventions should be chosen and deployed in a timely fashion by the social worker and other members of the renal team. These interventions should include depression screening, psychosocial education and counseling regarding coping strategies to facilitate adjustment to illness, cognitive-behavioral counseling, grief counseling, brief marital and family support counseling, solution-oriented counseling, problem-solving, and referral for psychiatry or urology if needed to obtain medications and treatment for depression and sexual dysfunction. THE PATIENT SHOULD SIGN THIS CARE PLAN THAT THEY HAVE BEEN OFFERED THESE INTERVENTIONS. THE RISK OF THESE INTERVENTIONS NOT BEING DEPLOYED IS VERY HIGH. This is in part because of the lack of time-support the MSW has to deploy these needed interventions. This lack of

time is the result of the assignment of the MSW to non-professional tasks such as completing insurance forms and arranging travel. I believe that a regulatory pressure to provide these social services would result in the administrators across the country finally accepting the need to provide social services to the patients, rather than just psychosocial assessment without intervention.

(6209-1)
494.90 Patient Plan of Care

In this section you have defined the skills of the MSW in facilitating patient adjustment to illness and promoting rehabilitation. I think language requiring the responsibility of the Social Worker to provide social work treatment within the profession's current standards is important. Currently, there is more assessment than treatment being offered to dialysis patients. Furthermore, social workers choose to assess the psychosocial problem and not treat it, and instead choose to refer to outside behavioral or mental health providers are having no success in getting patients to follow up on that referral. Nephrology social workers know firsthand the disappointing numbers of patients that pursue these referrals. I myself conducted one of the most important studies in this area across several dialysis companies in the greater San Diego area.

Johnstone, S, LeSage L, and the San Diego Chapter of Nephrology Social Workers: "The key role of the nephrology social worker in treating the depressed ESRD patient: patient utilization preferences and implications for on-site staffing practices" (manuscript in progress) 1998.)

I think it is imperative that the new regulations prescribe SW treatment within the dialysis facility. The following models of treatment, which are now brief (1-6 sessions), easy to deliver and readily available to the MSW, should be considered within the scope of service to be offered to the dialysis patient at the clinic to improve treatment outcomes:

1. depression screening
2. mental status screening
3. brief cognitive-behavioral treatment for depression(groupwork or individual)
4. brief cognitive-behavioral treatment for anxiety (groupwork or individual)
5. brief marital or family counseling
6. mediation (for patient disruption)
7. anger management intervention
8. grief and loss counseling
9. problem solving (to help patients isolate and narrow concerns and solutions)
10. motivational interviewing to promote improved adherence behavior
11. brief cognitive behavioral interventions for treatment non-adherence
12. education re sexual dysfunction in CKD
13. referral to resources that reduce financial stress

I RECOMMEND THAT YOU REMOVE ANY LANGUAGE SUCH AS **"IF" THE SOCIAL WORKER IS NOT ABLE TO PROVIDE THE NECESSARY SERVICES"** WHICH ALLOWS A FACILITY TO CHOOSE NOT TO LET THEM PROVIDE THEM. INSTEAD, I RECOMMEND THAT YOU INSERT

SOMETHING SUCH AS "IN SITUATIONS WHERE A SW HAS NOT BEEN SUCCESSFUL IN INTERVENING INTO THESE IDENTIFIED PROBLEMS, THE CARE PLAN SHOULD CONTINUALLY BE REVISED.
ONLY AS A LAST RESORT SHOULD THE SW CONSIDER REFERRAL TO AN OUTSIDE MENTAL HEALTH PROFESSIONAL, DUE TO THE LOW SUCCESS IN PATIENT FOLLOW UP, AND ALL SW EFFORTS AND TREATMENT PROVIDED MUST BE NOTED".

494.90(b)(2) I believe 30 days is not enough time to create a comprehensive plan of care. I recommend the Interdisciplinary team do a brief, short term plan of care at the 30 day mark, based on the 20-day assessment, and then complete a more formal plan of care at the 90 day point after the more formal re-assessment at 90 days.

(6215-2)
494.110(a)(2)(vii) I fully support any effort to include the requirement that facilities measure their actual performance in addition to the outcomes of that performance. I think this requirement is key to their true effort, as they must display their efforts more clearly and prepare for examination of their true efforts.

(6217-2)
494.110(a)(2)(vii) patient satisfaction and grievances are very important parts of the QAPI program.
6217-3) Regarding your solicitation of ideas on how evaluation and tracking of grievances can be used to improve outcomes, I would like to suggest that the patient sign the grievance tracker to note any interventions offered by the staff to him/her as a result of the grievance. This pt. involvement ensures that genuine efforts were truly made to restore patient trust and improve patient satisfaction.

(6222-1,6222-2) 494.140 Personnel Qualifications

494.140(d) I support the proposal to eliminate the grandfather clause from the existing requirements for social workers at 405.2102(f).

I also support the requirement for the MSW, which offers an additional 900 hours of training in bio-psycho-social assessment above and beyond the BSW professional. It also offers a person-in-environment model that exceeds the training offered to a psychologist or marriage and family therapist and provides additional skills at helping patients adapt their multi-faceted lives to chronic illness. The MSW requirement that you continue, and the MSW's training in assessing adjustment to illness in the context of the patient's life situation, is critical to the future of disease management in ESRD.

I strongly OPPOSE, however, the proposal to remove the requirement for clinical specialty in the MSW in the dialysis setting.

I firmly believe the failure over the last 20 years for the MSW to offer social work treatment services in the outpatient dialysis environment is that many "non-clinical"

MSW social workers were allowed to enter the environment. These unlicensed MSW's, with little training in clinical practice were not prepared for the complexities of the hemodialysis environment. They provide a good assessment, but are not as focused on providing treatment. The lisenced clinician or MSW with a clinical specialty has taken the time to prepare for clinical examinations and has had additional focus and training to prepare them to serve the clinical needs of the ESRD patient.

I personally have spent 20 years supervising many MSWs without clinical specialty. I continue to receive 3-5 calls per week from an MSW supervisee without clinical training for assistance, which leads me to believe they are not prepared to operate independently in the complex, clinically challenging environment of todays ESRD treatment setting. The following clinical problems, that occur frequently in the dialysis clinic environment, necessitate sound clinical skills and experienced brief intervention.

Common ESRD patient challenges such as those listed below require specialized clinical social work skills in response to the following psychosocial barriers to treatment outcomes that prevail in CKD patients:

1. Depression management

- Auslander, Dobrof & Epstein, 2001
- Dobrof, Dolinko, Lichtiger, Uribarri & Epstein, 2000
- Finkelstein & Finkelstein, 1999
- Hedayati et al., 2004
- Wuerth, Finkelstein, Ciarcia, Peterson, Kliger & Finkelstein, 2001
- Kimmel et al., 2000
- Paniagua, Amato, Vonesh, Guo & Mujais, 2005
- Shulman, Price & Spinelli, 1989
- Chen, Wu, Wang & Jaw, 2003
- Medical Education Institute, 2004

2. Anxiety management

- Auslander, Dobrof & Epstein, 2001
- Dobrof, Dolinko, Lichtiger, Uribarri & Epstein, 2000
- Iacono, 2005
- Sikon, 2000

3. Non-Adherent /Health Risk Behavior

- Johnstone S and Halshaw D: Making peace with fluid: social workers launch a cognitive behavioral intervention to reduce health-risk behavior. Nephrology News and Issues 17 (13): 20-31. December 2003.

- Beder, J., Mason, S., Johnstone, S., Callahan, M. B., & LeSage, L. (2003). Effectiveness of a social work psychoeductional program in improving adherence behavior associated with risk of CVD in ESRD patients. *Journal of Nephrology Social Work*, 22, 12-22.
- Lenart,1998
- Husebye, Westle, Styrvoky, & Kjellstrand, 1987
- Saran, 2003
- Dobrof, Dolinko, Lichtiger, Uribarri & Epstein, 2000
- Bame, Peterson & Wray, 1993
- Friend, Hatchett, Schneider & Wadhwa, 1997
- Christensen & Raichle, 2002

4. Multi-layer Response to Patient disruption (including use of behavioral treatment to reduce incidents and mediation)

- Johnstone S, Seamon VJ, Halshaw D, Molinari J, and Longknife K. "The use of mediation to manage patient-staff conflict in the dialysis clinic." Advances in Renal Replacement Therapy 4(4) 1997; 359-371.

5. Marital and family stress

- Fisher, 2003
- Fox & Swazey, 1979
- Leo, Smith & Mori, 2003
- Kimmel, 1990
- Benik, Chowanec & Devins, 1990
- Pelletier-Hibbert & Sohi, 2001
- Nichols & Springford, 1984
- White & Greyner, 1999
- Holley & Reddy, 2003
- Wu et al., 2001

6. Behavioral Management of Altered Mental Status

- *Note: in a recent review of 840 patients at our 12 dialysis facilities, it was discovered that 32% of patients were either diagnosed with a mental illness, suffered from dementia or had a current substance abuse disorder.—Johnstone, S : Internal CQI project, FMCNA-San Diego 1999.)*
- LeSage, L. "The role of the neprhology social worker in managing underlying mental illness in the ESRD patient: A clinical case study", publication pending, 1998.

7. Potential for suicide/harm to others

- Kurella, Kimmel, Young & Chertow, 2005

It is in light of this scope of professional assessment and treatment and my 20 years of professional experience, I suggest the regulation read this way:

1. An MSW with either a specialty in clinical practice AND a clinical license in the state where they practice if applicable

OR

2. An MSW with a relationship with a clinical social work supervisor that hold the above certification that offers regularly scheduled contact with the MSW to assist with treatment planning and supervise behavioral health and clinical social work intervention to ensure patient treatment outcomes. under and not educate the team on the skills they had to offer the dialysis patient.

We use the latter (# 2 above) arrangement at our clinics in California. This arrangement allows for me as a clinical lead to recruit the MSW in the event of a labor shortage, but yet ensure he/she is capable of delivering needed interventions in his/her clinics with her patients and families under my supervision. In my situation, I receive approximately 40 calls a week for the 9 MSWs (without clinical training or clinical licensure) for professional guidance in the above noted 10 categories. It has become clear to me that these MSWs could not be succeeding independently at all times in the dialysis setting in responding to the complexities of the times.

I am in full support of your attention in your discussion to the reality that many non-professional tasks such as insurance forms and travel are assigned to the MSW, preventing her/him further from delivering skilled and needed treatment to the dialysis population. I am in full support of this concern, and would like to suggest that you put the following type of sentence in the regulations to strengthen the requirement as follows:

"MSWs are expected to provide casework, assessment, groupwork and treatment planning services, and are not to be assigned nonprofessional tasks that could interfere with their ability and professional focus to do so."

(6229-2, 6229-3)
494.180(b)(1)

I am concerned that you have not proposed any federal staff-to patient ratios, for , in the field of nephrology, this in my opinion would be the only effective way of ensuring effective time for professional treatment planning and professional intervention. With no ratios, most social workers , dieticians and nurses find enough time to assess, but not to intervene. If you don't require a ratio (at least a ratio slide), I fear this will continue. But if you must leave ratios out of the regulations themselves, I absolutely feel you must require an acuity-based staffing plan that the dialysis clinic is responsible to work with.

494.180 Condition: Governance (6253-2)

494.180 (f) (3)and(4) Standard: **Discharge and transfer policies and procedures**
I support the requirement that the medical director ensures any discharge or transfer is necessary medically or because the patient's disruption cannot be managed with all team efforts. I firmly support your requirement for documentation of all efforts. I think you could strengthen this language with a requirement for an annual inservice of all direct care staff with regard to the policies and procedures for discharge and transfer.
Often, in the heat of a patient disruption, the manager is without "buy-in" from the treatment team to provide effort to manage the disruption, and is under pressure from the team to discharge any "difficult" patient.
If the team were routinely in-services on procedures and protocols for managing disruptive behaviors, they could feel more empowered to do so and not jump so quickly to the option of discharge. This problem, and difficulty managing it, is on the rise across the nation.
The renal team needs strategic training mandated. An annual in-service for all team members should include: engaging in genuine, professional exploration with the patient re his/her concerns, psycho-social in-service education of the renal team re complex pt. behavior, pt.-administrator problem-solving meetings, behavioral contracts, the use of mediation and even suspension with medical evaluation and treatment until the patient's behavior can be stabilized. These efforts should be performed prior to discharge of any patient unless there is imminent threat of violence.

IN SUMMARY, the MSW level social worker is at the core of disease management of the person with chronic kidney disease. The skills of the Nephrology Social Worker can help keep the ESRD program effective and cost-contained! No one else can do what we do in the area of providing on-site behavioral health intervention- and we are doing it stronger and better than we ever have....Out-sourcing mental health service delivery has failed. Social Workers are the largest providers of mental health services in our nation. *National Association of Social Workers Newsletter* 44:6:1, 1999.

Current Medicare Demonstration projects are incorporating nephrology social workers in the role of behavioral health provider in order to contain costs and improve treatment outcomes for a reason.

It is in the nation's best interest to maximize and protect the skilled role of the Nephrology Social Worker on the CKD interdisciplinary team.

Sincerely,

Stephanie Johnstone LCSW
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April 25, 2005

Centers for Medicare and Medicaid Services (CMS)
Department of Health and Human Services
Attention: CMS-3818-P
PO Box 8012
Baltimore, MD 21244-8012

Re: Comments on proposed ESRD 42 CFR Parts 400, 405, 412, 413, 414, 488, and 494

Dear Regulatory Comments Review Committee:

My comments come from my experience as a family member of a former ESRD patient who performed home hemodialysis and who was one of the first transplant patient's in Indiana. I am a Master's prepared Registered Nurse in Indiana. I work at a State Agency as the manager over ESRD facility surveys and at Indiana University School of Nursing as adjunct faculty. Please consider my comments on the proposed rules at 42 CFR Parts 494.

Provision of Proposed Part 494 Subpart A-General Provisions:

Basis and Scope (Proposed 494.1)

"Basis" ESRDs regulation *should include* regulations that mandate survey frequency at least every three (3) years and follow up surveys annually for two (2) years where the facility is non-compliant to one or more of the Conditions of Participation (CoP).

"Basis" Dollars *should be allocated* to conduct federal ESRD surveys to ensure surveys are conducted as mandated and to ensure patient safety.

"Basis" Language *should* address sanctions to ESRD clinics that restrict admission or if ESRD clinics discharge patients based on patient requiring higher skill care issues (vent dependent patients), mobility issues (bed-bound, or obesity) where the patient is unable to get dialysis at an outpatient ESRD. This practice cost the patient significantly in quality of life and is costly when the patient can only secure help at the hospital in an emergency situation.

Definitions (Proposed 494.10)

"Definitions" CMS *should* cross reference definitions to ensure inconsistencies do not exist within the regulations proposed. The definition for Interdisciplinary team *should be* the same definition throughout the regulations. Refer to proposed definition at Plan of Care section (propose 494.80) that states, "The interdisciplinary definition proposed states, "the interdisciplinary team consist of, at a minimum, the patient (if he or she desires) or his/her designee, a registered nurse, a nephrologists or physician treating the patient for ESRD, a social worker, and a dietitian." The definition at Plan of Care *is the desired definition.*

"Definition" Patient residence and Patient home are different and CMS should consider adding to the definitions to the regulation in the area of home dialysis and hemodialysis in nursing homes. Patient residence may be any residence where the patient is living such as personally owned home, SNF, NF, Group home, assistive living. Patient personal home may be the primary dwelling of the patient that is not operated or owned by others for the purpose of providing, offering or assisting with support services.

Definitions continued (Proposed 494.10)

"Definition" *I would oppose* the regulations allowing hemodialysis being offered into group homes, assistive living, and nursing homes etc. that are not federally regulated. The federal government *may want to add language to limit* hemodialysis care to "patient residents" managed by facilities that are regulated federal facilities.

"Definition" Home dialysis *should be* specific when defining. Recent trends have home dialysis extending into different components of "patients residence". Patient residence could extend into a variety of managed owned residents such as skilled nursing homes, residential centers, group homes, assistive living etc.

Provisions of Proposed Part 494 Subpart B (Patient Safety)

Water Quality (Proposed 494.40)

"Water Quality" Water quality is essential to the health and safety of all dialysis patients. Agrees with updating the water standards by using American National Standards Institute) AAMI as proposed is essential for improving outcomes, staying current, decreasing risk and reducing cost related to complications. CMS *should further amend* this section to strengthen Water Quality by adding that CMS Central Office staff may approve and mandate future AAMI or International Standards by Program Memorandum provided a process is in place to involve the regulatory commission over the Department of Health and Human Services (DHHS).

Reuse of Hemodialyzers and Bloodlines (Proposed 494.50)

"Reuse of hemodialyzers and bloodlines" The new proposals *should have* stronger penalties for facilities that violate cleaning recommendations and that prohibits facilities from performing reuse when unsafe practices are repeatedly cited as deficient practices.

"Reuse of hemodialyzers and bloodlines" Reuse increases risk to dialysis patients and more stringent regulations should be adopted. Agree with the proposal *to maintain the existing regulations and to adopt the more current AAMI guidelines and manufactures recommended guidelines* as care in this area must be current with national and international standards.

"Reuse of hemodialyzers and bloodlines" CMS *should further amend* this section to strengthen reuse standards by adding that CMS Central Office staff may approve and mandate future AAMI or International standards by Program Memorandum provided a process is in place to involve the regulatory commission over the Department of Health and Human Services (DHHS) provided a process is in place to involve the regulatory commission over the Department of Health and Human Services (DHHS).

Physical Plant (Proposed 494.60

"Physical Environment" Agree with adopting the National Fire Protection Associations (NDPA) Life Safety Code (LSC).

"Physical Environment" Support the use of life safety surveys for ESRD facilities; however, the *mandate needs to include funding* to conduct life safety inspections.

"Physical Environment" Agree with *adding* fire safety language, equipment maintained by manufactures recommendations and standards.

"Physical Environment" Agree with *additions* for emergency preparedness and disaster plans, monitoring, and training staff on use of emergency equipment since many ESRD facilities employ unlicensed nonprofessionals to provide health care.

Proposed Part 494 Subpart C (Patient Care)
Patients' Rights (Proposed 494.70)
"Patients' Rights" Agree with informing patients of their rights prior to beginning treatment.
"Patients' Rights" A statement *should be* included that prohibits the ESRD facilities from discriminating against patient when admitting or discharging related to disability or the need for more skilled care such as ventilator dependent, cart bound, and severe obesity. Hospitals emergency rooms should not have to treat ESRD patients on a routine basis.
Patient Assessment (Proposed 494.80)
"Patients' Rights" Patient rights *should propose* protection for patients when the patient is forced to sign AMA forms before the patient may be disconnected, especially when the patient is noncompliant to policies that may be violating a persons right or dignity.
"Patients' Rights" Stronger language *should be added* to require the ESRD facility to provide and post the different ways a patient may file a complaint with the State Agency (SA) and Network. Legible, current and accurate telephone numbers and hours of operation should be posted in legible print.
"Patients' Rights" The public statement *should state* the patient or family may file a complaint directly with the SA or Network prior to filing the grievance with the facility.
"Patients' Rights" Many ESRD patients fear retaliation, so the proposed rules *should have* language addressing this.
"Patients' Rights" A statement *should be* included in patient rights regarding the patient has a right to be free from sexual, verbal or physical abuse, intimidation and harassment.
Patient Assessment (Proposed 494.80)
"Patient assessment" Agree with the statement in the proposed rules regarding the importance of comprehensive patient assessment by a group of professionals (physician, registered nurse, social worker, and dietitian) and the areas that should be addressed.
"Patient assessment" The proposed language *should also state* that routine patient assessments and reassessments that are performed prior to initiating care and when complications arise during treatment be performed by a professional registered nurse. Most State Nursing Practice Acts have the registered nurse performing assessment and reassessments not licensed practical nurses or unlicensed technicians.
"Patient assessment" *Would strongly oppose to any regulatory language in the ESRD proposed rules that would expand the practice of medicine or the practice of nursing to licensed practical nurses and unlicensed technician. CMS ESRD regulations should use caution and not interfere with other State regulatory bodies (Federal and State) that have authority to establish practice standards and rules.*
Patient Plan of Care (Proposed 494.90)
"Plan of Care" I support one plan of care that meets all the patients ESRD needs based on the comprehensive assessment by professionals. However, the definition of "Interdisciplinary Team" *should be consistent at this section and the definitions section.*
"Plan of Care" I *would support* the definition for interdisciplinary team to read, "The interdisciplinary team consist of, at a minimum, the patient (if he or she desires) or his/her designee, a registered nurse, a nephrologists or physician treating the patient for ESRD, a social worker, and a dietitian."
"Plan of Care" The plan of care *should address* issues that the facility wishes to restrict; however, the plan of care should not violate individual's rights to choose and be involved in care regardless if the decision is not in the best interest of the patient.

Development of the Patient Plan of Care (Proposed 494.90(a)(1))

Dose of Dialysis (Proposed 494.90(a)(1))

"Plan of Care -Dose of dialysis" The proposed rules *should reflect* an assessment by the registered nurse or physician and a written order by a physician prior to changing flow rates, run times, changing treatments, medications, or fluids.

"Plan of Care-dose of dialysis" Frequently ESRD facilities have allowed unlicensed technicians to perform patient assessments and perform treatments without the involvement of professional interdisciplinary team member, the registered nurse or physician order. The proposed language *should restrict this practice.*

"Plan of Care-dose of dialysis" The proposed rules on nutrition are detailed; the patient care plan of care *should include* more detail.

Vascular Access (Proposed 494.90(a)(4))

"Plan of Care-Vascular Access" The vascular access is the lifeline to the dialysis patient. The proposed regulations *should address* issues associated to patient outcomes.

"Plan of Care-Vascular Access" Vascular access is a national concern and Fistula's First is just one initiative. Vascular Access is a concern for patients as found on the CMS Webb site, "Evaluation of the Content of the Dialysis Facility Compare Website: Final Report" April 2004, page 45-48. CMS *should* consider consumers concerns regarding care issues.

"Plan of Care-Vascular Access" Vascular access requires skill and judgment to perform so that the lifeline of the patient is maintained and potential harm such as death does not occur from poor technique. Vascular access should only be performed by registered nurses or licensed practical nurses that have been trained to perform this highly technical skill. Currently, access is being performed by unlicensed personnel, many without proper training or the professional knowledge to assess for potential complications until it is too late. Language *should be included that restricts this practice.*

Implementation of the Patient Plan of Care (Proposed 494.90(b))

"Plan of Care" I would *oppose* any regulatory language increasing the time for comprehensive assessment to annual because the dialysis patient's needs change frequently and it is reasonable that the professional team, that are onsite most days, should have the opportunity to conduct the comprehensive assessment more frequently than once a year.

"Plan of Care- Implementation of Patient Plan of Care" The dialysis patient and care is highly technical and complicated. The reassessment and comprehensive plan of care *should be* completed at a minimum of every (3) three to six (6) months for stable patients and monthly for unstable patients with addendums attached to reflect changes in between comprehensive assessment.

Patient Education and Training (Proposed 494.90(d))

"Plan of Care- Patient Education and Training" Patient education and training is essential to positive patient care outcomes. The proposals language *should be expanded* especially for dialysis that is being performed in the home setting or nursing home environment.

Condition: Care at Home (Proposed 494.100)

"Care at Home" Proposed rules *should reflect* the professional staff such as the registered nurse, should evaluate, maintain the plan of care and educate the patient on home dialysis care in conjunction with the physician, dietician and social worker.

Condition: Care at Home Continued (Proposed 494.100)

"Care at Home" Trained assistants *should be* defined in the definitions and *should not* be unlicensed staff *employed by* ESRD facility or nursing home. Trained assistants *should be* those individuals that are either family members or significant others or that the patient is hiring or using to assist them with home dialysis.

Dialysis of the ESRD Patient in the Home Setting

"Care at Home-Dialysis of the ESRD Patient in the Home Setting" We agree with proposal that the same standards apply in the home setting as the outpatient setting.

"Care at Home-Dialysis of the ESRD Patient in the Home Setting" Strongly agree that the facility *should be involved and provide all* of the support services, regardless of whether the dialysis supplies are provide by the dialysis facility or a durable medical company.

Dialysis of ESRD Patients in Nursing Facilities and Skilled Nursing Facilities

Delineation of Responsibility

"Care at Home-Delineation of Responsibility" The ESRD facility *must maintain responsibility* for the dialysis of patients in Nursing Facilities and Skilled Nursing Facilities and a written agreement *should be* in place delineating services and responsibilities.

Applicable ESRD Conditions of Coverage

"Care at Home-Applicable ESRD Conditions of Coverage" All of the Conditions of Coverage should apply to care provided at the NF and SNF that apply to ESRD facilities.

Nursing Coverage

"Care at Home-Nursing Coverage" Dialysis is highly technical and is constantly changing. Extensive training is required for experienced registered nurses when transferring to work in ESRD facilities. The nursing coverage in the proposed rules *should mandate and define* an experienced ESRD registered nurse to be on duty at the NF and SNF while patients are receiving dialysis. In most State Nursing Practice Acts, the licensed practical nurse is a delegated nursing service and therefore should not be responsible for the supervision of care provided at NF and SNF. The licensed practical nurse should work *under the on-site* direction of an experienced ESRD registered nurse. Patients in the NF and SNF typically have multiple co-morbidities and require even more skill to assess and reassess, so the patients in NF ands SNF should not receive care from staff with less expertise and knowledge.

Training

"Care at Home-Training" *Agree with* any proposed language where the certified ESRD facility staff is completely responsible for all training of ESRD and dialysis care completed in the NF and SNF to patients, family or staff.

Monitoring

"Care at Home-Monitoring" Agree that the certified ESRD facility staff *should be* responsible for monitoring of the ESRD patient's care related to dialysis and dialysis related issues.

Condition: Quality Assessment and Performance Improvement (QAPI) (Proposed 494.110)

"QAPI" Agree with the proposed requirements for the ESRD facility to have a QAPI and to perform.

Program Scope (Proposed 494.110 (a))

"QAPI" Agree with the areas proposed, *may want to consider* adding language regarding equipment problems, staffing problems, other errors, etc.

"QAPI" May want to *add language* regarding the facility should initiate action to QA issues found and will measured for improved outcomes.

Facility Specific Standards for Enforcement (Proposed 494.110(d))
"QAPI" *Agree with issues* identified by the OIG *but disagree that with issues* raised by the facilities. ESRD facilities *should be* held accountable to minimum standards of care.
Condition: Clinical Standards
"Clinical Standards" Agree with having a condition for clinical standards. A condition is needed to ensure clinical standards are maintained and a means to enforce deficient practice when it occurs. *The rules should propose this section.*
Standard: Performance Expectations
"Clinical Standards- Dose of dialysis"
"Clinical Standards" The proposed rules *should reflect* an assessment by the registered nurse or physician prior to changing flow rates, run time or treating and administering treatments for changes in the patient's medical condition. Frequently, ESRD facilities allow unlicensed renal technicians to perform patient assessments and treatments without the involvement or direct supervision of professional registered nurse or physician and without physician orders. The proposed rules on nutrition are detailed; the clinical standards section *requires more detail.*
"Clinical Standards- Additional clinical standards"
"Clinical Standards" Agree somewhat; however, CMS *should seek input* for clinical standards for nursing and the delegation of nursing from the National Council State Boards of Nursing, State Nursing Boards, and the National Nursing Associations and National Nursing Associations Specialties.
"Clinical Standards- Additional clinical standards" CMS *should use caution and not* suggest ESRD regulations that contradict State Nurse Practice Acts and Medical Practice Acts by introducing language of unlicensed renal technicians to perform nursing. The use of unlicensed personnel for the performance of nursing care may not enhance the quality of patient care in technical and critical areas that require advanced knowledge and judgment.
Provision of Proposed Subpart D: Administration
Personnel Qualifications (Proposed 494.140)
"Personnel Qualifications"
Nursing Services (Proposed 494.140(b))
"Personnel Qualifications-Nursing Service" Agree with having four distinct categories defined for nursing responsibility based on duties of the registered nurse.
"Personnel Qualifications" #1. Nurse responsible for nursing services at the facility: Agree with the qualifications that each facility employ a full time registered nurse with the proposed experience.
"Personnel Qualifications" For numbers # 2 and # 3, nurse responsible for training in self care and in charge of the unit: agree with a professional being responsible each shift; agree the nurse *should be* a registered nurse. *Disagree that the nurse could be a licensed practical nurse* as the proposal may violate individual State Nurse Practice Acts. CMS *should use caution* when introducing regulatory language that may introduce conflicting standards/rules that are enforced and regulated by other State and Federal entities and rules. The nursing shortage should not justify the use of unqualified staffs.
"Personnel Qualifications"# 4. Care on the unit for nursing service: Agree that licensed practical nurses may be able to provide care on the unit under the direct onsite supervision of a registered nurse provided the regulations do not introduce care that is direct conflict with individual State Practice Acts.

Dietitian (Proposed 494.140 (c))

"Personnel Qualifications-Dietitian" Agree provided the rules proposed do not overstep the boundaries of the dietitian and regulatory body that govern individual State Dietitians Practice Acts.

Social Worker (Proposed 494.140(d))

"Personnel Qualifications-Social Worker" Agree with proposed regulations. A masters degree is already expected, *oppose grandfathering*. CMS should also seek input from entities that regulate Social Work.

Dialysis Technicians (Proposed 494.140(e))

"Personnel Qualifications-Dialysis Technicians" *Opposed to* any regulatory language that suggest the use of unlicensed personnel for the practice of nursing or the practice of medicine. CMS should use caution when introducing regulatory language in the ESRD regulations that could conflict with individual State Nurse Practice Acts and Medical Practice Acts. CMS is not the regulatory body over individual State Practice Acts and introducing conflicting regulations will create unnecessary issues. Regardless that ESRD facilities use renal technicians for care, the use of unlicensed personnel in lieu of registered nurses is extremely dangerous and has had documented negative outcomes.

Other Personnel

"Personnel Qualifications- Other personnel" Agree with pharmacy being a part of the interdisciplinary team where applicable.

Condition: Responsibilities of Medical Director (Proposed 494.150)

"Responsibilities of Medical Director" Agree with keeping medical director as a separate condition as suggested by the Office of Inspector General (OIG). I *would propose* stronger language holding Medical Director and owner/governing body responsible.

"Responsibilities of Medical Director" Agrees with maintain the requirement of responsibility of the unit having adequate trained staff.

"Responsibilities of Medical Director" We agree that the medical director should be responsible and involved with ESRD facility policy oversight and compliance.

"Responsibilities of Medical Director" Agree the medical director oversee the interdisciplinary team follows the policies and procedures.

Relationship With ESRD Network (494.160)

"ESRD Network" Patient care complaints *should be* sent to the SA regulatory body that conducts surveys and not the Network. I would agree that The Network *should not* be included in the regulations and at times question the role of ESRD Networks and at times question the dollars allocated to the Network.

Condition: Medical Records (494.170)

"Medical Records" *Agree* with the proposal to maintain complete medical records for all patients under the ESRD facilities supervision including home patients and durable medical equipment.

"Medical Records" *Disagree* that CMS does not establish some standardization of what should minimally contained in the medical records, CMS should not assume a facility will maintain standardize records unless CMS describes what they would want to have in the medical records.

"Medical Records" *Disagree* with eliminating written policies and procedure for recordkeeping. Policies and procedures establish written guidelines for all staff to follow.

Condition: Governance (Proposed 494.180)
"Governance" Comments are given under each subcategory under governance.
"Governance- Existing Requirements for Governing Bodies" *Agree* with current language under the existing requirements.
"Governance- Overview of the Proposed Governance Requirements" *Agrees* with proposal that requires necessary minimum administrative features that are responsive to patients and that strengthen the accountability of the governing body.
"Governance- Governance Condition" (Proposed 494.180) *Agrees* with the proposed language that the governing body be under control of an identifiable governing body, or designated person(s) so function, with full legal authority and responsibility for the governance and operation of the facility.
"Governance- Governance Condition" Would *suggest adding* stronger language and penalties to ownership/governing body for repeated deficient practices since most ESRD facilities are owned by four major corporations. The medical directors and facility directors may not be able to implement change because of the governing body/ownership corporations dictating facility policy.
"Governance- Designation of a Chief Executive Officer or Administrator" (Proposed 494.180(a)) *Agrees* with proposed language regarding the CEO/administrators role.
"Governance- Adequate Number of Qualified and Trained Staff" (Proposed 494.180(b))
Agrees with having minimum staffing ratios; however, stronger language regarding the ratios for registered nurse to renal technician should be given since ESRD is highly technical.
"Governance- Adequate Number of Qualified and Trained Staff" *Propose* that the registered nurse not just be available, but that the registered nurse is a directed patient care giver and provides the direct supervision of care. *Propose* the administrative registered nurse be responsible for the overall operations and not be counted as a registered nurse in the daily direct care ratios.
"Governance- Adequate Number of Qualified and Trained Staff" (Proposed 494.180(b))
"Governance- Adequate Number of Qualified and Trained Staff" *Agree* that renal technicians need regulatory language if the renal technicians role is expanding from reuse to patient care, nursing and clinical areas. However, individual states do not agree on the renal technician's role, practices, and the training program because technician roles are crossing over into the practice of nursing and the practice of medicine. CMS *should use caution* when introducing "standards" for unlicensed personnel into federal ESRD regulatory language when existing State rules promulgate the practice of nursing or may prohibit unlicensed personnel performing under nursing. The nursing shortage should not be exploited to substitute substandard care and non-professional staff such as technicians to perform the duties of nursing in a highly technical medical area that requires knowledge, judgment, and constant assessment with nursing interventions. The proposed language is suggesting that CMS supports the use of unlicensed personnel for nursing and is setting precedence for changes in the practice of nursing and the practice of medicine that could create problems with enforcement for unsafe practices.
"Governance- Adequate Number of Qualified and Trained Staff" *Propose* that CMS introduce language that allows for renal technicians only where they are nationally certified and where State laws clearly allow this practice.

"Governance- Adequate Number of Qualified and Trained Staff" Continued (Proposed 494.180(b))

"Governance- Adequate Number of Qualified and Trained Staff" *Further propose* language that addresses caution where state law does not regulate unlicensed personnel for nursing or where state law is noncommittal to the issue. Any language regarding technicians should support current national standards as outlined by the certification groups for renal technicians. Renal technicians should have limited responsibilities in the clinical setting unless they are nationally certified, and evidence of extensive training, and where State law supports unlicensed personnel. "Governance- Adequate Number of Qualified and Trained Staff" *Oppose any* language where ESRDs are allowed to police their own training programs.

"Governance-Furnishing Services" (Proposed 494.180(d))

We agree with proposed language; however, *propose additional* language regarding home dialysis.

"Governance-Internal Grievance Process" (Proposed 494.180(e))

We agree with proposal; however, *propose additional language* regarding the expectation with timely investigation, documentation, and resolution to grievance along with QA to prevent future issues or reoccurrence.

"Governance-Discharge and Transfer Policies and Procedures" (Proposed 494.180(f))

Agrees with some of the proposed language. *Proposed* the adding of language for admission policy that discourages discrimination.

"Governance-Discharge and Transfer Policies and Procedures" Also, the regulations *should address* procedures regarding the ESRD making arrangements and paying for services provided at a local hospital for treatment they refuse to provide when they wish to discontinue a disruptive patient. The payment and arrangements should continue until an internal or external hearing can be conducted and/or a mental health evaluation to evaluate if the behavior was related to a disability, medication, dialysis, etc. and could be treated. Based on findings, the facility could then provide discharge with notice and assist with transfer to another facility. Discharging to hospital emergency room for care is not acceptable for managing this disease.

"Governance-Furnishing Data and Information for ESRD Program Administration" (Proposed 494.180(h))

Agree that data and information from ESRD programs *should be* mandatory instead of voluntary. "Governance-Furnishing Data and Information for ESRD Program Administration" Provisions *should be* available to make the data public such as home health compare etc. so the public may make informed consent when choosing an ESRD facility.

"Governance-Furnishing Data and Information for ESRD Program Administration" *Propose* that regulations contain language to allow for audits by The Networks regarding accuracy of data that has been submitted since the data submitted is self reported. Many ESRDs have data available directly from their computerized systems with machines and documentation.

"Governance- Disclosure of Ownership" (Proposed 494.180(i))

Agrees with proposal, *consider adding* language where the facility must report all administrative changes to the State surveying agency, including administration, changes in address, and telephone numbers.

Other Proposed Changes and Issues

Proposed Additions to Part 488 "Part 488" agrees with adding Subpart H to Part 488 that included the existing sanction provisions, termination procedures, alternative sanctions denial of payment, notice procedures, and rights of suppliers.

Reference Materials
New Provisions of Part 494
"Part 494 - new provisions" agrees with format, but please refer to comments above regarding infection control, water quality, physical environment, patient rights, patient assessment, patient plan of care, care at home, quality assessment and performance improvement, special purpose renal dialysis facilities, personnel qualifications responsibilities of the medical director, and governance.

Thank you for the opportunity to comment. If you desire further clarification, feel free to contact me at the address and telephone numbers below.

Sincerely,

Lana K Richmond MSN, RN BC

Lana K. Richmond, MSN, RN, BC
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04/28/2005

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention:CMS-3818-P
P.O. Box 8012
Baltimore, MD 21244-8012

To Whom It May Concern,

Enclosed are comments written by members of the Council of Nephrology Social Workers. As a member of the CNSW, I strongly support these recommended changes to the proposed Conditions for Coverage.

In addition, I have also typed a second list of suggestions that I would like to see reviewed during the comment period. I work as a member of an ESRD Network, and feel that the additional suggestions would reduce patient complaints and facility concerns regarding the care that is received in dialysis facilities across the country.

Thank you for allowing me the opportunity to submit these comments.

Cris Pickering, MSW

Subpart B – PATIENT SAFETY

§494.30 Condition: Infection Control
(a) Standard: Procedures for infection control
(1) We support using the Centers for Disease Control recommendations for infection control.

§494.60 Condition: Physical environment
We support the requirements of this section.

(c) Standard: Patient care environment
(2)(i) We support the requirement to keep the facility at a temperature comfortable for the majority of the patients.

(d) Standard: Emergency Preparedness
(3) We support the need for defibrillators in the dialysis facility.

We recommend that the current regulation at 405.2140 (b)(3) be retained "There is a nursing/monitoring station from which adequate surveillance of patients receiving dialysis services can be made."

Subpart C – PATIENT CARE

§494.70 Condition: Patients' rights
(a) Standard: Patients' rights
We support all of the patients' rights included in this section.

We recommend the addition of a patient's right to perform self care dialysis after successful completion of a training program.

(2) In addition to the patient receiving information in a way he/she can understand, we recommend retaining language from the current regulations at 405.2138 (c) "Provision is made for translators where a significant number of patients exhibit language barriers."

(5) We recommend that this be reworded to state the patient must "be educated on advance directives" rather than just "informed". We also recommend the patient has a right for their advance directives to be honored by the facility.

(b) Standard: Right to be informed regarding the facility's discharge and transfer policies
(1) We recommend the patient be informed of the facility discharge policies within 30 days of admission to the clinic.

(c) Standard: Posting of Rights
We support posting the phone numbers for the Network and State agency.

§494.80 Condition: Patient Assessment

(a) Standard: Assessment criteria
We support the assessment criteria, especially vascular access type and maintenance, vocational rehabilitation status and modality selection. We recommend adding language that would allow the Secretary to modify or update the criteria as new technology and knowledge become available.

(b) Standard: Frequency of assessment for new patients.

(1) We suggest the initial assessment be completed within 30 calendar days rather than 20 and that this regulation specify "first dialysis treatment at the dialysis facility" so it is not confused with the patient's first treatment in the hospital or other dialysis facility.

(d) Standard: Patient reassessment
(2) We support the definition of unstable patient and the need to assess unstable patients monthly.

§494.90 Condition: Patient plan of care
We suggest "The interdisciplinary team" be defined in the same way it is at 494.80 "...consisting of, at a minimum, the patient (if the patient chooses) or the patient's designee, a registered nurse, a nephrologist or the physician treating the patient for ESRD, a social worker, and a dietitian..."

We also recommend that a patient's refusal to participate in the care plan be documented in the plan of care.

(a) Standard: Development of patient plan of care

We recommend that the patient's advance directives be included in the patient plan of care.

(4) We support the vascular access assessment and suggest it be strengthened by adding a requirement that for any patients not dialyzing via a fistula the plan document the reasons a fistula is not being used and a plan for fistula placement for eligible patients.

(6) We recommend that Functional Status be included as part of the rehabilitation section of the patient care plan.

(b) Standard: Implementation of the patient plan of care
(1) We recommend the patient plan of care be signed by the patient's attending physician.

(c) Standard: Transplantation referral tracking
We support the requirements for transplantation referral tracking.

§494.100 Condition: Care at Home

We recommend that this section be modified to address patients performing self care dialysis in the dialysis facility or that a separate section be added. The conditions need to address policies and procedures for self care in the facility, staff and patient training and a clear definition of self care dialysis.

(c) Standard: Support Services
(1)(i) We suggest "periodic monitoring" be modified to say "at least annually".

§494.110 Condition: Quality assessment and performance improvement
We support the requirements for a facility QI program.

(a) Standard: Program scope
We recommend the addition of patient satisfaction as one of the measures.

Subpart D-ADMINISTRATION

§494.140 Condition: Personnel qualifications
(a) Standard: Medical Director
(1) We recommend the Medical Director needs to be Board eligible.

(d) Standard: Social worker
We support the requirement for the social worker to hold a master's degree in social work.

(e) Standard: Patient care dialysis technicians
We support specific requirements for dialysis technicians.

(3) We recommend that the requirement for technicians to receive training in "communication and interpersonal skills including patient sensitivity training and care of difficult patients" be required at least annually and that it be required for all patient care staff, not just technicians.

§494.150 Condition: Responsibilities of the medical director
We support the revised language for medical director responsibilities, especially (c)(2)(i) requiring the medical director to ensure all policies and procedures are adhered to by all individuals who treat patients in the facility. We recommend the medical director be given the ability and authority to monitor and improve the care provided by attending nephrologists.

We recommend that dialysis facilities appoint only one Medical Director at any given time to avoid confusion as to who is responsible. We currently have 81 facilities who report having more than one Medical Director. 44 with two Medical Directors, 18 with three Medical Directors, 5 with four Medical Directors, 9 with five Medical Directors, 2 with six Medical Directors, 3 with seven Medical Directors on record.

We recommend that the Medical Director be responsible for ensuring the facility complies with the goals of and acts upon recommendations from the ESRD Network.

§494.160 Condition: Relationship with the ESRD Network
We recommend that "statement of work" be replaced with "goals and objectives" to be consistent with the legislation and that the language in the current regulations §405.2134 "participate in network activities" be retained.

§494.170 Condition: Medical Records
(c) Standard: Record retention and preservation
We recommend the regulation specify what information must be kept in the active patient's chart, readily available. §405.2139 of the current regulation provides language: "(a) Standard: medical record. Each patient's medical record contains sufficient information to identify the patient clearly, to justify the diagnosis and treatment, and to document the results accurately. All medical records contain the following general categories of information: Documented evidence of assessment of the needs of the patient, whether the patient is treated with a reprocessed hemodialyzer, of establishment of an appropriate plan of treatment, and of the care and services provided (see Sec. 405.2137(a) and (b)); evidence that the patient was informed of the results of the assessment described in Sec. 405.2138(a)(5); identification and social data; signed consent forms referral information with authentication of diagnosis; medical and nursing history of patient; report(s) of physician examination(s); diagnostic and therapeutic orders; observations, and progress notes; reports of treatments and clinical findings; reports of laboratory and other diagnostic tests and procedures; and discharge summary including final diagnosis and prognosis."

§494.180 Condition: Governance
We recommend retaining the language from the current regulations, §405.2136 Condition: Governing body and management, (d) Standard: personnel policies and procedures and (f)(3) of that section "The facility policy provides that, whenever feasible, hours for dialysis are scheduled for patient convenience and that arrangements are made to accommodate employed patients who wish to be dialyzed during their non-working hours and (g) of that section Standard: medical supervision and emergency coverage.

(b) Standard: Adequate number of qualified and trained staff
(1) We recommend that "adequate number of qualified personnel" be replaced with staffing ratios, using the recommendations to the professional organizations if available – Nurses – 1:10, Direct patient care staff 1:4, Social workers 1:75, Dietitians 1:125.

(2) We support the requirement that a registered nurse be present at all times. We recommend this language be clarified to state the registered nurse must be in the immediate clinical care area, not just in the building.

(4) We suggest this language be modified to "All employees are provided continuing education and related development activities"

(5) We recommend that the training program cover each of the required topics at least annually.

(5) We recommend that (ii) Care of patients with kidney failure, including interpersonal skills be expanded to include communication and sensitivity training and that it be required for all staff, not just dialysis technicians.

We recommend that all staff be trained on the principles of Quality Improvement and quality standards and on the role of the ESRD Network.

(c) Standard: Medical staff appointments
We recommend that the governing body authorize and require the medical director to monitor and improve the performance of all attending nephrologists in the facility.

(f) Standard: Discharge and transfer policies and procedures
(4) We support the reassessment of the patient prior to discharge.

(4)(ii) We support the requirement that medical director and attending physician must sign the discharge orders.

(4)(iv) We support the requirement that the dialysis facilities notify the ESRD Network of involuntary discharges and transfers. We suggest this be modified to require facilities to notify the Network prior to the discharge unless it involves an immediate threat to the health and safety of others, in which case the facility should notify the Network within 48 hours of the discharge.

Council of Nephrology Social Workers Comment
Proposed Transplant Regulations file code CMS–3835–P

***Issue Identifier*: 482.90 Condition of participation: Patient and living donor selection**
***Comment*:** We support the mandate of a psychosocial evaluation for all prospective transplant candidates. We suggest changing the language of this condition from "psychosocial evaluation" to "qualified social worker evaluation."
***Rationale*:** There are numerous psychosocial barriers to transplantation. The chronicity of End Stage Renal Disease and the intrusiveness of required treatment such as transplantation provide renal patients with multiple psychosocial stressors including: cognitive losses, social isolation, bereavement, coping to chronic illness, concern about mortality & morbidity, depression, anxiety, psycho-organic disorders, somatic symptoms, lifestyle, economic pressures, insurance and prescription issues, employment and rehabilitation barriers, mood changes, body image issues, concerns about pain, numerous losses (income, financial security, health, libido, strength, independence, mobility, schedule flexibility, sleep, appetite, freedom with diet and fluid), social role disturbance (familial, social, vocational), dependency issues, and diminished quality of life (DeOreo, 1997; Gudes, 1995; Katon & Schulberg, 1997; Kimmel et al., 2000; Levenson, 1991; Mapes, 2004; Rabin, 1983; Rosen, 1999; Vourlekis & Rivera-Mizoni, 1997). Psychosocial factors such as finances, depression, relationship changes and employment lead to transplant immunosuppressant noncompliance (Russell & Ashbaugh, 2004). The gravity of these psychosocial factors necessitate an evaluation/assessment conducted by a qualified social worker- utilizing language such as "psychosocial evaluation" is not recommended because there could be ambiguity about who conducts such an evaluation; we recommend using the language of a "qualified social worker evaluation" instead. There should be an effort to standardize and uniformly include some of the essential elements of the recommended psychosocial evaluation. This would also allow for the development of more valid and reliable interventions as well as psychosocial outcome measures. The ESRD Network of Texas' (2002) Social Services Practice Recommendations *http://www.esrdnetwork.org/professional_standards.htm* include recommendations for these essential social work evaluation elements and may be used as a suggested template.

***Issue Identifier*: 482.90 Condition of participation: Patient and living donor selection**
***Comment*:** We support the mandate of a psychosocial evaluation for all prospective living donors. We suggest changing the language of this condition from "psychosocial evaluation" to "qualified social worker evaluation." We support a requirement that transplant centers performing living donor transplants must provide the service of an independent donor advocacy team that includes a qualified social worker. We suggest that living donors and recipients should have, whenever possible, separate qualified practitioners conducting the social work and medical evaluations.
***Rationale*:** Living donor kidney transplants are increasingly popular. Meeting appropriate psychosocial criteria is essential to the success of the transplant. Qualified social workers must assess the donor in order to gauge any normative pressures on the donor that may influence the decision to donate a kidney, motivation for donation, ability to make informed consent, the nature of the relationship between the donor and recipient, and the donor's psychosocial status (Fisher, 2003; Fox & Swazey, 1979; Leo, Smith & Mori, 2003). The gravity of these psychosocial factors necessitate an evaluation/assessment conducted by a qualified social worker- utilizing language such as "psychosocial evaluation" is not recommended because there could be ambiguity about who conducts such an evaluation; we recommend using the language of a "qualified social worker evaluation" instead. There should be an effort to standardize and uniformly include some of the essential elements of the recommended psychosocial evaluation for living donors. This would also allow for the development of more valid and reliable interventions as well as psychosocial outcome measures. The ESRD Network of Texas' (2002) Social Services Practice Recommendations *http://www.esrdnetwork.org/professional_standards.htm* include recommendations for these essential elements and may be used as a suggested template for a social work assessment.

We believe that an independent donor advocacy team that includes a qualified social worker would ensure that the informed consent standards meet ethical principles as they are applied to the practice of all living organ transplantation. Social workers have an established place in health care ethics committees and in helping patients make ethical decisions. A qualified social worker is essential on an advocacy team to assess inappropriate motivations to or inadequate understanding of the related psychosocial issues of donation.

As transplant recipients and donors may have conflicting interests and motivation, it is strongly encouraged that living donors and recipients should have, whenever possible, separate qualified social workers to minimize potential conflict of interests.

***Issue Identifier*: 482.94 Condition of participation: Patient and living donor management**
Comment: We support (d) Standard: Social services [The transplant center must make available social services, furnished by qualified social workers, to transplant patients, living donors, and their families. A qualified social worker is an individual who meets licensing requirements in the State in which practicing], and (d)(1) [Has completed a course of study with specialization in clinical practice, and holds a masters degree from a graduate school of social work accredited by the Council on Social Work Education.] However, we do not support: (d) (2): [Has served for at least 2 years as a social worker, one year of which was in a transplantation program, and has established a consultative relationship with a social worker who is qualified under § 82.94], and urge that issue identifier: §482.94 (d) (2) be removed from the proposed changes. Additionally, CNSW believes that there is need for ongoing access to qualified transplant social workers, who would ideally be dedicated to the transplant program.

Rationale: Transplant patients present with highly complex needs on an individual as well as systems level. Master's level social workers are trained to intervene within both areas of need that are essential for optimal patient functioning, and help facilitate congruity between individuals and their environments' resources, demands and opportunities (Coulton, 1979; McKinley & Callahan, 1998; Morrow-Howell, 1992; Wallace, Goldberg, & Slaby, 1984). Social workers have an expertise of combining social context and utilizing community resource information along with knowledge of personality dynamics. The master in social work degree (MSW) provides an additional 900 hours of specialized training beyond a baccalaureate degree in social work. An MSW curriculum is the only curriculum, which offers additional specialization in the Bio-Psycho-Social-Cultural, Person-in-Environment model of understanding human behavior. Undergraduate (B.S.W.) degrees, or other mental health credentials (M.A. in counseling, sociology, psychology or Ph.D. in Psychology, etc.) do not offer this specialized and comprehensive training in bio-psycho-social assessment and interaction between individual and social systems that is essential in transplant programs. The National Association of Social Workers Standards of Classification considers the Baccalaureate degree as a basic level of practice (Bonner & Greenspan, 1989; National Association of Social Workers, 1981). Under these same standards, the Masters in Social Work degree is considered a specialized level of professional practice and requires a demonstration of skill or competency in performance (Anderson, 1986). Masters-prepared social workers are trained in conducting empirical evaluations of their own practice interventions (Council on Social Work Education). Empirically, the training of a masters-prepared social worker appears to be the best predictor of overall performance, particularly in the areas of psychological counseling, casework and case management (Booz & Hamilton, Inc., 1987; Dhooper, Royse & Wolfe, 1990). The additional 900 hours of specialized, clinical training prepares the MSW to work autonomously in the transplant setting, where supervision and peer support is not readily available. This additional training in the biopsychosocial model of understanding human behavior also enables the masters-prepared social worker to provide cost-effective interventions such as assessment, education, individual, family and group therapy and to independently monitor the outcomes of these interventions to ensure their effectiveness.

The chronicity of End Stage Renal Disease and the intrusiveness of required treatment such as transplantation provide renal patients with multiple psychosocial stressors including: cognitive losses, social isolation, bereavement, coping to chronic illness, concern about mortality & morbidity, depression, anxiety, psycho-organic disorders, somatic symptoms, lifestyle,

***Issue Identifier*: 482.98 Condition of participation: Human resources**
***Comment*:** We support changing the language of this condition from "The team must be composed of individuals with the appropriate qualifications, training, and experience in the relevant areas of medicine, nursing, nutrition, social services, transplant coordination, and pharmacology." to "The team must be composed of individuals with the appropriate qualifications, training, and experience in the relevant areas of medicine, nursing, nutrition, **social work**, transplant coordination, and pharmacology."
***Rationale*:** As discussed in our comments for identifiers 482.90 and 482.94, the gravity of psychosocial factors related to transplantation necessitate Master's level qualified social work interventions. Utilizing language such as "social services" is not recommended because there could be ambiguity about who provides such services; we recommend using the language of a "social work" instead.

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Issue Identifier	CNSW Comment on Conditions for Coverage for End Stage Renal Disease Facilities File code CMS–3818–P pg 1
LOCATION OF COC	PROPOSED DIALYSIS COC that are identified in this document can be found at: http://a257.g.akamaitech.net/7/257/2422/09feb20050800/edocket.access.gpo.gov/2005/pdf/05-1622.pdf
494.10 Definitions Dialysis facility *NEW* Staff assisted skilled nursing home dialysis	***Add:*** A new category for dialysis provided in a nursing home setting ***Rationale***: Nursing home dialysis is typically provided by staff. Home dialysis (PD or home hemodialysis) is typically performed by a trained *patient* and/or a helper. Making these treatments equivalent ignores the important differences between them, including the staff training/supervisory needs of nursing home dialysis patients. ***Reference:*** Tong & Nissenson, 2002
494.20. Condition Compliance with Federal, State, and local laws and regulations	***Add:*** "Facilities must accommodate mobility, hearing, vision, or other disabilities or language and communication barriers" ***Rationale***: Healthcare settings are covered entities under the Americans with Disabilities Act. ***References:*** ADA
494.60 Condition Physical Environment. (c) Patient care environment	***Add to c1***: Require facilities to be accessible to people with disabilities. ***Rationale***: Americans with Disabilities Act ***Reference:*** ADA ***Add to c1***: Require facilities to have a place for confidential interviews with patients and families and to provide for privacy during body exposure. ***Rationale***: HIPAA privacy ***Reference:*** *Protecting the Privacy of Patients' Health Information* ***Comment***: CNSW Supports the inclusion of the proposed (c) (2) regarding facility temperature. ***Rationale***: A common complaint from dialysis patients is in regards to the facility climate. A patient-centered care approach dictates that facilities need to have a plan in place to accommodate patients' preferences for climate, and address the concerns of patients who are not comfortable.
494.70 Condition Patients' Rights (a) Standard: Patients' rights	***Add***: (2) Require facility to ask the patient to *demonstrate understanding* of information provided. ***Rationale***: Without this requirement, it would be very easy for staff to believe that they had informed a patient without realizing that, in fact, the patient did not understand the information. ***References:*** Johnstone, 2004; Juhnke & Curtin, 2000; Kaveh & Kimmel, 2001 ***Comment & Addition to a6:*** CNSW supports the language of a6 with the recommended addition of requiring facilities to inform patients of all available treatments (in-center hemodialysis, CAPD, CCPD, conventional home hemodialysis, daily home hemodialysis, nocturnal home hemodialysis, transplant), and to provide a list of facilities where treatments are offered within 120 miles if the facility does not offer that treatment. ***Rationale:*** We propose to require that a facility inform patients about all available treatment modalities

Issue Identifier	CNSW Comment on Conditions for Coverage for End Stage Renal Disease Facilities File code CMS–3818–P pg 2
	and settings, so patients can make an informed decision regarding the most appropriate course of treatment that meets their needs. To assist dialysis patients in achieving the optimal quality of life, patients need education about each modality and must have access to the widest array of treatment choices possible. For patients to truly have choices in their modalities, they must not only know what types of treatment exist, but where they can be obtained. Home Dialysis Central (www.homedialysis.org) has a searchable database of clinics that offer any type of home dialysis and US maps for each home modality showing a 120 mile radius from clinic locations. ***Comment:*** CNSW supports the language of a5 ***Rationale:*** Advance directives establish in writing an individual's preference with respect to the degree of medical care and treatment desired or who should make treatment decisions if the individual should become incapacitated and lose the ability to make or communicate medical decisions. ***Add***: (new 17) "Have access to a qualified social worker and dietitian as needed" ***Rationale:*** Social workers and dietitians often have large caseloads, cover multiple clinics and/or work part-time, and patients often do not know how to contact them when needed. ***References:*** Bogatz, Colasanto, Sweeney, 2005; Forum of ESRD Networks, 2003; Merighi & Ehlebracht, 2004a ***Add***: (new 18) "Be informed that full- or part-time employment and/or schooling is possible on dialysis" ***Rationale:*** New patients do not know what to expect from dialysis and may be told that they must go on disability, when paid employment (with insurance) or schooling may be possible for them, particularly if they have access to evening shifts, transplant or home dialysis therapies. The purpose of dialysis is to permit the highest possible level of functioning despite kidney failure, thus this element of rehabilitation is crucial. ***References:*** Curtin et al,1996; Rasgon et al, 1993, 1996 ***Add***: (new 19) "Have a work-friendly modality (PD or home hemodialysis) or schedule that accommodates work or school" ***Rationale:*** Same as above for new 18. ***References:*** Same as above for new 18, plus:Mayo 1999 ***Add***: (new 20) "Receive referral for physical or occupational therapy, and/or vocational rehabilitation as needed" ***Rationale:*** These interventions have been shown to improve patient rehabilitation outcomes. ***References:*** Beder, 1999; Dobrof et al., 2001; Witten, Howell & Latos, 1999.

Add: (new 21) "Attend care planning meetings with or without representation."
Rationale: Promoting patient participation in care requires that patients have the right to attend their own care planning meetings.

Add: (new 22) "Request an interdisciplinary conference with the care team, medical director and/or nephrologists."
Rationale: Patients don't realize that they can convene a care conference, and this is one way to obtain feedback from the team outside of the normal care planning meeting, which might only be done once/year.

Add: (new 23) "Refuse cannulation by a nurse or technician if access problems occurred with that staff member in the past until evidence of retraining is provided. Patients may also request another staff person to observe cannulation."
Rationale: Patients have only a limited number of potential vascular access sites, and if a staff person was responsible for causing access damage or hospitalization in the past, patients must have the right to protect themselves by refusing care from that staff person. Despite the obvious interpersonal and convenience issues this will cause for facilities, this is a patient safety issue that also has the potential to reduce cost to the system of hospitalization from vascular access problems. This will also encourage clinics to help their staff improve their cannulation skills and teach patients to self-cannulate.

Add: (new 24) "Be informed that self-cannulation is possible and be offered training to self cannulate."
Rationale: Having a single, consistent cannulator can help preserve vascular accesses and reduce hospitalizations. Since the patient is always present for the hemodialysis treatment, he or she should be encouraged whenever possible to become his/her own cannulator. Clinics should not be allowed to have a policy denying a willing patient the right to learn to self-cannulate.

Add: (new 25) "Be informed of topical analgesics for needle pain and how to obtain them"
Rationale: Needle fear and needle pain are largely unaddressed issues in hemodialysis, despite the large (14-15 gauge) needles that must be used at each treatment. Patients should be able to undergo a painless treatment, and low-cost, over-the-counter, 4% lidocaine preparations are available that will not harm the access and will provide pain relief. Patients should be told that these products exist and where to obtain them.
Reference: McLaughlin et al., 2003

Add: (new 26) "Receive counseling from a qualified social worker to address concerns related to the patient's adjustment to illness, including changes to life-style and relationships because of his illness, developmental issues affected by his illness, and any behavior that negatively affects his health or standing in the facility."

	Rationale: Patients are faced with numerous adjustment issues due to ESRD and its treatment regimes. Master's level social workers are trained to intervene within areas of need that are essential for optimal patient functioning and adjustment ***References:*** McKinley & Callahan, 1998; Vourlekis & Rivera-Mizzoni, 1997
494.70 Condition Patients' Rights (b) Standard: Right to be informed regarding the facility's discharge and transfer policies.	***Add to b1***: "Receive counseling and support from the team to resolve behavioral issues and be informed of behaviors that will lead staff to notify police or refer for evaluation of risk to self or others" ***Rationale***: Facilities should be encouraged first to try counseling to resolve difficult situations ***References:*** Forum of ESRD Networks, 2003; Johnstone S, et al, 1997; King & Moss, 2004; Rau-Foster, 2001; Renal Physicians Association and American Society of Nephrology, 2000 ***Add***: (new 2) "Not be involuntarily discharged from the facility for non-adherence with the treatment plan, including missing or shortening in-center hemodialysis treatments, excessive fluid weight gain, or lab tests that would suggest dietary indiscretions unless it can be shown that the patient's behavior is putting other patients or the facility operations at risk." ***Rationale:*** The ESRD Networks and the preamble of these proposed Conditions for Coverage have both stated that non-compliance should not be a basis for involuntary discharge from lifesaving dialysis treatment. Patients often are not educated as to the reasons why these behaviors may be harmful to them; it is therefore inappropriate to refuse them care due to their lack of knowledge. If consistent difficulties are noted with a patients' ability to follow the treatment plan, a team evaluation should be initiated to investigate and address all potential factors. For example, a patient who is trying to maintain a full-time job to support a family may choose to leave treatment early rather than risk losing employment; or a patient who is taking a medication that causes dry mouth may be unable to follow the fluid limits for in-center hemodialysis. ***References:*** Forum of ESRD Networks, 2003; Johnstone S, et al., 1997; King & Moss, 2004; Rau-Foster, 2001; Renal Physicians Association and American Society of Nephrology, 2000 ***Change***: (renumbered 3) Delete or define "reducing...ongoing care." ***Rationale:*** This phrase is unclear.
494.70 Condition Patients' Rights (c) Standard: Posting of rights.	***Add***: "Facilities with patients who cannot read the patients' rights poster must provide an alternate method to inform these patients of their rights which can be verified at survey." ***Rationale & References***: Americans with Disabilities Act, Civil Rights Act
494.80 Condition Patient assessment (a) Standard: Assessment criteria.	***Change***: The language of "social worker" in the first sentence to "qualified social worker" ***Rationale***: This will clarify any ambiguity of the social work role. ***Add***: (a1) "...and functioning and well-being using the SF-36 or other standardized survey that permits reporting of or conversion to a physical component summary (PCS) score and mental component

summary (MCS) score and all domains of functioning and well-being measured by that survey. If the MCS or mental health domain score is low, assess for major depression using the PHQ-2 or another validated depression survey or referring the patient to further mental health evaluation."
Rationale: The preamble to the *Conditions for Coverage* discussed the importance of measuring functioning and well-being—but stated that there was "no consensus" about which measure to use. In fact, the literature clearly supports the value of the PCS and MCS scores to independently predict morbidity and mortality among tens of thousands of ESRD patients—and these scores can be obtained from any of the tools currently in use to measure functioning and well-being. The composite scores (PCS and MCS) have been proven to be as predictive of hospitalization and death as serum albumin or Kt/V. Scores can be improved through qualified social work interventions.
References; DeOreo, 1997; Kalantar-Zadeh, Kopple, Block, Humphreys, 2001; Knight et al. 2003; Kroenke, Spitzer & Williams, 2003; Lowrie, Curtin, LePain & Schatell, 2003; Mapes et al., 2004

Comment: CNSW supports the language of a2, a3, a4, a5, a6

Change: (a7) to "Evaluation of psychosocial needs (such as but not limited to: coping with chronic illness, anxiety, mood changes, depression, social isolation, bereavement, concern about mortality & morbidity, psycho-organic disorders, cognitive losses, somatic symptoms, pain, anxiety about pain, decreased physical strength, body image issues, drastic lifestyle changes and numerous losses of [income, financial security, health, libido, independence, mobility, schedule flexibility, sleep, appetite, freedom with diet and fluid], social role disturbance [familial, social, vocational], dependency issues, diminished quality of life, relationship changes; psychosocial barriers to optimal nutritional status, mineral metabolism status, dialysis access, transplantation referral, participation in self care, activity level, rehabilitation status, economic pressures, insurance and prescription issues, employment and rehabilitation barriers)."
Rationale: Much like the elaboration of a1, a4, a8, a9, elaborating what "psychosocial issues" entails will ensure national coherence of the exact psychosocial issues that must be assessed for each patient. There is clear literature that identifies these psychosocial issues throughout this response.

Comment: CNSW supports the language of a8

Add: (a9)(new i) "The facility must include in its evaluation a report of self-care activities the patient performs. If the patient does not participate in care, the basis for nonparticipation must be documented in the medical record (i.e., cognitive impairment, refusal, etc.)."
Rationale: Life Options research has found that patients on dialysis 15 years or longer who participated actively in their own care did better; follow-up research with a random sample of 372 in-center hemodialysis patients found participation in self-care is correlated with higher functioning and well-being, which, in turn, predicts reduced hospitalization and mortality.

Issue Identifier	
	References: Curtin, Bultman, Schatell & Chewning, 2004; Curtin & Mapes, 2001 ***Add***: (9)(new ii) "If the patient is not referred for home dialysis, the basis for non-referral must be documented in the medical record. Lack of availability of home dialysis in the facility is not a legitimate basis for non-referral." ***Rationale:*** Requiring that the basis for non-referral for home dialysis be documented will help to ensure that patients have access to these therapies and will provide needed data for QAPI purposes. ***Comment:*** CNSW supports the language of a10, a11, a12, a13
494.80 Condition Patient assessment (b) Standard. Frequency of assessment for new patients	***Change***: (b1) to "An initial comprehensive assessment and patient care plan must be conducted within 30 calendar days after the first dialysis treatment." ***Rationale***: We recommend combining an initial team assessment and care plan as they work in concert: a care plan should address areas for intervention as identified in the assessment. Permitting 30 days for assessment and development of a care plan allows for full team participation and adequate assessment of patient needs. ***Comment:*** CNSW supports the language of b2
494.80 Condition Patient assessment (d) Standard: Patient reassessment	***Change***: (d2iii) to "significant change in psychosocial needs as identified in 494.80 a7." ***Rationale***: Referring back to the specific psychosocial issues recommended to be added to 494.80 a7 will eliminate any ambiguity of needs to reassess ***Add***: (v) "Physical debilitation per patient report, staff observation, or reduced physical component summary (PCS) score on a validated measure of functioning and well-being." ***Rationale:*** Low PCS scores predict higher morbidity and mortality in research among ESRD patients. ***References:*** DeOreo, 1997; Kalantar-Zadeh, Kopple, Block, Humphreys, 2001; Knight et al. 2003; Kroenke, Spitzer & Williams, 2003; Lowrie, Curtin, LePain & Schatell, 2003; Mapes et al., 2004 ***Add***: (new vi) "Diminished emotional well-being per patient report, staff observation, or reduced mental component summary (MCS) score on a validated measure of functioning and well-being." ***Rationale:*** Low MCS scores predict higher morbidity and mortality in research among ESRD patients. Low MCS scores are also linked to depression and skipping dialysis treatments. ***References:*** DeOreo, 1997; Kalantar-Zadeh, Kopple, Block, Humphreys, 2001; Knight et al. 2003; Kroenke, Spitzer & Williams, 2003; Lowrie, Curtin, LePain & Schatell, 2003; Mapes et al., 2004 ***Add***: (new vii) "Depression per patient report, staff observation or validated depression screening survey" ***Rationale:*** Multiple studies report a high prevalence of untreated depression in dialysis patients;

Issue Identifier	
	depression is an independent predictor of death. ***References;*** Andreucci et al., 2004.; Kimmel, 1993; Kimmel, 1998; Kutner et al., 2000.; Wuerth, Finklestein & Finklestein, 2005 ***Add***: (new viii) "Loss of or threatened loss of employment per patient report" ***Rationale***: Poor physical and mental health functioning have been linked to increased hospitalizations and death. Loss of employment is linked to depression, social isolation, financial difficulties, and loss of employer group health plan coverage. Identifying low functioning patients early and targeting interventions to improve their functioning should improve their physical and mental functioning and employment outcomes. ***References;*** Blake, Codd, Cassidy & O'Meara, 2000; Lowrie, Curtin, LePain & Schatell, 2003; Mapes et al., 2004; Witten, Schatell & Becker, 2004
494.90 Condition Patient plan of care. (a) Standard: Development of patient plan of care.	***Add***: (a) the *patient* to those developing the plan and include: "If the patient or his or her representative does not participate in care planning, the basis for nonparticipation must be noted in the patient's medical record, the patient or his or her representative must initial the reason provided, and sign the care plan." ***Rationale***: The patient must be explicitly listed as part of the care planning process ***Add***: (new 3) "*Psychosocial status*. The interdisciplinary team must provide the necessary care and services to achieve and sustain an effective psychosocial status." ***Rationale & References***: Eighty-nine percent of ESRD patients report experiencing significant lifestyle changes from the disease (Kaitelidou, et al., 2005). The chronicity of end stage renal disease and the intrusiveness of its required treatment provide renal patients with multiple disease-related and treatment-related psychosocial stressors that affect their everyday lives (Devins et al., 1990). Researchers including Auslander, Dobrof & Epstein (2001), Burrows-Hudson (1995), and Kimmel et al. (1998) have found that psychosocial issues negatively impact health outcomes of patients and diminish patient quality of life. Therefore, "psychosocial status" must be considered as equally important as other aspects of the care plan. ***Add***: (new 6) Home dialysis status. All patients must be informed of *all* home dialysis options, including CAPD, CCPD, conventional home hemodialysis, daily home hemodialysis, and nocturnal home hemodialysis, and be evaluated as a home dialysis candidate. When the patient is a home dialysis candidate, the interdisciplinary team must develop plans for pursuing home dialysis. The patient's plan of care must include documentation of the (i) Plan for home dialysis, if the patient accepts referral for home dialysis; (ii) Patient's decision, if the patient is a home dialysis candidate but declines home dialysis; or (iii) Reason(s) for the patient's non-referral as a home dialysis candidate as documented in accordance

Issue Identifier	
	with § 494.80(a)(9)(ii) of this part. ***Rationale***: Home therapies allow greater flexibility, patient control, fewer dietary and fluid restrictions, need for fewer medications, potential for improved dialysis adequacy, and improved likelihood of employment. CMS has stated encouragement of home dialysis as a goal. Every patient must be informed of home dialysis options, evaluated for candidacy for home dialysis, and, if not a candidate, the reason(s) why not should be reported. This allows quality assessment and improvement activities to be undertaken in the area of home dialysis. ***Add***: (renumbered 8) "Rehabilitation status. The interdisciplinary team must provide the necessary care and services to: (i) maximize physical and mental functioning as measured minimally by physical component summary (PCS) score and mental component summary (MCS) score on a validated measure of functioning and well-being (or an equally valid indicator of physical and mental functioning), (ii) help patients maintain or improve their vocational status (including paid or volunteer work) as measured by annually tracking the same employment categories on the CMS 2728 form (iii) help pediatric patients (under the age of 18 years) to obtain at least a high school diploma or equivalency as measured by annually tracking student status. (iv) Reasons for decline in rehabilitation status must be documented in the patient's medical record and interventions designed to reverse the decline." ***Rationale***: The goals of the current proposed section are vague, not measurable, and not actionable. To improve rehabilitation outcomes, facilities must meet certain standards. From the perspective of the Medical Education Institute, which administers the Life Options Rehabilitation Program, "rehabilitation" can be measured by a functioning and well-being vocational assessment. Functioning and well-being (measured minimally as PCS and MCS) predict morbidity and mortality. Annually tracking employment status through Networks using the same categories on the CMS 2728 and including this as a QAPI would improve the likelihood that rehabilitation efforts would be successful.
494.90 Condition Patient plan of care. (b) Standard: Implementation of the patient care plan.	***Add to 3b***: "If the expected outcome is not achieved, the interdisciplinary team must describe barriers encountered, adjust the patient's plan of care to either achieve the specified goals or establish new goals, and explain why new goals are needed." ***Rationale***: When goals are not met, barriers must be identified and goals re-examined for feasibility of success. Sometimes barriers can be eliminated so original goals can be met; other times, new goals must be set that are more reasonable.
494.90 Condition Patient plan of care. (c) Standard: Transplantation referral tracking	***Comment:*** CNSW supports the language of (c) and recommends its inclusion in the final conditions. In addition, we would also like to see language which would outline the responsibilities of transplant centers and their responsibilities for following up and informing dialysis units of the transplant status of patients referred for transplant.

Issue Identifier	CNSW Comment on Conditions for Coverage for End Stage Renal Disease Facilities File code CMS–3818–P pg 9
494.90 Condition Patient plan of care. (d) Standard: Patient education and training.	***Add to d***: "The patient care plan must include, as applicable, education and training for patients and family members or caregivers or both, and must document training the following areas in the patient's medical record: (i) The nature and management of ESRD (ii) The full range of techniques associated with treatment modality selected, including effective use of dialysis supplies and equipment in achieving and delivering the physician's prescription of Kt/V or URR, and effective erythropoietin administration (if prescribed) to achieve and maintain a hemoglobin level of at least 11 gm/dL (iii) How to follow the renal diet, fluid restrictions, and medication regimen (iv) How to read, understand, and use lab tests to track clinical status (v) How to be an active partner in care (vi) How to achieve and maintain physical, vocational, emotional and social well-being (vii) How to detect, report, and manage symptoms and potential dialysis complications (viii) What resources are available in the facility and community and how to find and use them (ix) How to self-monitor health status and record and report health status information (x) How to handle medical and non-medical emergencies (xi) How to reduce the likelihood of infections (x) How to properly dispose of medical waste in the dialysis facility and at home **Rationale**: Life Options Research has demonstrated among 372 randomly-selected in-center hemodialysis patients that higher levels of dialysis knowledge are correlated with higher mental component summary (MCS) scores on the SF-12, which are, in turn, predictive of longer survival and lower hospitalization. The specific aspects of education delineated above are what Life Options believes to be core skills that ESRD patients must gain in order to become active partners in care, producing their own best health outcomes and monitoring the safety and quality of the care that is delivered to them. ***References;*** Curtin, et al. 2002; Curtin, Klag, Bultman & Schatell, 2002; Curtin, Sitter, Schatell & Chewning, 2004; Johnstone, et al., 2004
494.100 Condition Care at home.	***Comment:*** CNSW agrees that services to home patients should be at least equivalent to those provided to in-center patients. **Rationale**: Home dialysis patients are patients of the ESRD facility and are entitled to the same rights, services, and efforts to achieve expected outcomes as any other patient of the facility. ***Add***: (new 3iv) "Implementation of a social work care plan" ***Rationale & References***: Eighty-nine percent of ESRD patients report experiencing significant lifestyle changes from the disease (Kaitelidou, et al., 2005). The chronicity of end stage renal disease and the intrusiveness of treatment provide renal patients with multiple disease-related and treatment-related psychosocial stressors that affect their everyday lives (Devins et al., 1990). Researchers including Auslander, Dobrof & Epstein (2001), Burrows-Hudson (1995), and Kimmel et al. (1998) have found that

Issue Identifier	
	psychosocial issues negatively impact health outcomes of patients and diminish patient quality of life. Therefore, a social work care plan is as equally important as other aspects of training for home patients. It is important to specify a "social work care plan" to ensure that it is conducted by a qualified social worker as identified below.
494.100 Condition Care at home. (c) Standard: Support services.	***Add to 1i***: "Periodic monitoring of the patient's home adaptation, including at minimum an annual visit to the patient's home by all facility personnel if geographically feasible (RN, social worker, dietitian, and machine technician) in accordance with the patient's plan of care." ***Rationale***: Members of the interdisciplinary team can offer better care to patients after seeing the patient in his/her home environment where they can observe barriers and supports first-hand. The members should be specified to ensure equal visitation of the team members across all dialysis units. The language of this part of the proposed conditions is vague and subject to varying interpretation (i.e. exactly who are the "facility personnel" who will visit the patient's home?) ***Add to 1iv***: "Patient consultation with all members of the interdisciplinary team, as needed." ***Rationale***: The language of this part of the proposed conditions is vague and subject to varying interpretation
NEWCONDITION Staff assisted skilled nursing home dialysis	***Add:*** A new condition for dialysis provided in a nursing home setting (that is not incorporated into the "home" condition 494.100) ***Rationale***: Nursing home dialysis is typically provided by staff. Home dialysis (PD or home hemodialysis) is typically performed by a trained patient and/or a helper. Making these treatments equivalent obscures important differences between them, including the staff training/supervisory needs of nursing home dialysis patients. To include care in a nursing facility/skilled nursing facility (NF/SNF) under "care at home" is inappropriate. There is a tremendous difference in what CMS must do to protect the health and safety of highly functioning, trained patients who do self-care at home (or have assistance from a trained helper at home) and patients who require personnel in an NF/SNF to perform dialysis because they are too debilitated to travel to a dialysis facility. ***Reference:***Tong & Nissenson, 2002 ***Add:*** Language to this proposed condition that would mandate " A Nursing facility/Skilled Nursing Facility providing full-care dialysis to residents with ESRD, must be certified as a dialysis facility and comply with all sections of this rule, including personnel qualifications." ***Rationale***: Patients receiving dialysis in NF or SNF should not be deprived of essential services that they would normally receive in an outpatient dialysis facility, including consultation with a qualified nephrology social worker. While NFs and SNFs may employ social workers, these social workers may not hold a master's degree and will not have the specialized knowledge of the complex social and emotional factors affecting the dialysis patient. To ensure that the health and safety of NF or SNF hemodialysis patients is protected, any proposed requirements should specifically incorporate Secs 494.70, 494.80 and 494.90 of

	the proposed conditions of coverage.
§494.110 Condition Quality assessment and performance improvement. (a) Standard: Program scope.	***Add***: (1) "The program must include, but not be limited to, an ongoing program that achieves measurable improvement in physical, mental, and clinical health outcomes and reduction of medical errors by using indicators or performance measures associated with improved physical and mental health outcomes and with the identification and reduction of medical errors." ***Rationale:*** To ensure patient-centered care, patient functioning and well-being must be one of the quality indicators that is monitored and improved. ***Add***: (2)(new iii) "Psychosocial status." ***Rationale & References***: Eighty-nine percent of ESRD patients report experiencing significant lifestyle changes from the disease (Kaitelidou, et al., 2005). The chronicity of end stage renal disease and the intrusiveness of its required treatment provide renal patients with multiple disease-related and treatment-related psychosocial stressors that affect their everyday lives (Devins et al., 1990). Researchers including Auslander, Dobrof & Epstein (2001), Burrows-Hudson (1995), and Kimmel et al. (1998) have found that psychosocial issues negatively impact health outcomes of patients and diminish patient quality of life. Therefore, "psychosocial status" must be considered as equally important as other aspects of quality improvement. CNSW has many resources and tools, available through the National Kidney Foundation, that can be used to track social work quality. ***Add***: (2)(new ix) "Functioning and well-being as measured by physical component summary (PCS) and mental component summary (MCS) scores (or other equally valid measure of mental and physical functioning) and vocational status using the same categories as reported on the CMS 2728 form" ***Rationale:*** These scores provide a baseline and ongoing basis for QAPI activities to improve patient rehabilitation outcomes. ***Comment:*** CNSW agrees that dialysis providers must measure patient satisfaction and grievances. CNSW supports the use of a standardized survey (such as the one being currently developed by CMS) for measuring patients' experience and ratings of their care. Such a survey would provide information for consumer choice, reports that facilities can use for internal quality improvement and external benchmarking against other facilities, and finally, information that can be used for public reporting and monitoring purposes. The survey should be in the public domain and consist of a core set of questions that could be used in conjunction with existing surveys.
494.140 Condition Personnel qualifications	***Comment:*** CNSW recommends that this section be renamed "Personnel qualifications and responsibilities", with the addition of specified personnel responsibilities to each team member's qualifications. If it is decided that adding "personnel responsibilities" to this section is inappropriate, we would suggest the alteration of 494.150 to be renamed "Condition: Personnel Responsibilities" and include a discussion of the responsibilities of each team member (instead of just the medical director as is

currently proposed). CNSW suggests possible responsibilities for social workers in the next section, where we comment on "494.140 Condition Personnel qualifications (d) Standard: Social worker." These suggestions can be used in a new "responsibilities" section.

Rationale & References: It is critically important to clearly delineate personnel responsibilities in some fashion in these new conditions of coverage to ensure that there is parity in the provision of services to beneficiaries in every dialysis unit in the country. It is just as important to outline each team member's responsibilities as it is the medical director's, as is currently proposed. This is especially important regarding qualified social work responsibilities. Currently, many master's level social workers are given responsibilities and tasks that are clerical in nature and which prevent the MSW from participating fully with the patient's interdisciplinary team so that optimal outcomes of care may be achieved. It is imperative that the conditions of coverage specify the responsibilities of a qualified social worker so that dialysis clinics do not assign social workers inappropriate tasks and responsibilities. Tasks that are clerical in nature or involve admissions, transportation, travel, billing, and determining insurance coverage prohibit nephrology social workers from performing the clinical tasks central to their mission (Callahan, Witten & Johnstone, 1997). Russo (2002) found among the nephrology social workers that he surveyed 53% were responsible for making transportation arrangements for patients, and 46% of the nephrology social workers in his survey were responsible for making dialysis transient arrangements (which involved copying and sending patient records to out-of-town units). Only 20% of his respondents were able to do patient education. In the Promoting Excellence in End-of-Life Care 2002 report, End-Stage Renal Disease Workgroup Recommendations to the Field, it was recommend that dialysis units discontinue using master's level social workers for clerical tasks to ensure that they will have sufficient time to provide clinical services to their patients and their families. Merighi and Ehlebracht (2004b; 2004c; 2005), in a survey of 809 randomly sampled dialysis social workers in the United States, found that:

- 94% of social workers did clerical tasks, and that 87% of those respondents considered these tasks to be outside the scope of their social work training.
- 61% of social workers were solely responsible for arranging patient transportation.
- 57% of social workers were responsible for making travel arrangements for patients who were transient, which required 9% of their work time.
- 26% of social workers were responsible for initial insurance verification.
- 43% of social workers tracked Medicare coordination of benefit periods.
- 44% of social workers were primarily responsible for completing patient admission paperwork.
- 18% of social workers were involved in collecting fees from patients. (Respondents noted that this could significantly diminish trust and cause damage to the therapeutic relationship).
- Respondents spent 38% of their time on insurance, billing and clerical tasks vs. 25% of their

	time spent assessing and counseling patients. • Only 34% of the social workers thought that they had enough time to sufficiently address patients' psychosocial needs. This evidence clearly demonstrates that without clear definition and monitoring of responsibilities assigned to the qualified social work (as is the current case), social workers are routinely assigned tasks that are inappropriate, preventing them from doing appropriate tasks. For all of these reasons, CNSW is strongly urging the addition of "personnel responsibilities" to the new conditions of coverage (either in this section, or the next section).
494.140 Condition Personnel qualifications (d) Standard: Social worker.	***Change the language of d to***: *Social worker.* The facility must have a qualified social worker who—(1) Has completed a course of study with specialization in clinical practice, and holds a masters degree from a graduate school of social work accredited by the Council on Social Work Education; (2) Meets the licensing requirements for social work practice in the State in which he or she is practicing; and (3) Is responsible for the following tasks: initial and continuous patient assessment and care planning including the social, psychological, cultural and environmental barriers to coping to ESRD and prescribed treatment; provide emotional support, encouragement and supportive counseling to patients and their families or support system; provide individual and group counseling to facilitate adjustment to and coping with ESRD, comorbidities and treatment regimes, including diagnosing and treating mood disorders such as anxiety, depression, and hostility; providing patient and family education; helping to overcome psychosocial barriers to transplantation and home dialysis; crisis intervention; providing education and help completing advance directives; promoting self-determination; assisting patients with achieving their rehabilitation goals (including: overcoming barriers ; providing patients with education and encouragement regarding rehabilitation; providing case management with local or state vocational rehabilitation agencies); providing staff in-service education regarding ESRD psychosocial issues; recommending topics and otherwise participating in the facility's quality assurance program; mediating conflicts between patients, families and staff; participating in interdisciplinary care planning and collaboration, and advocating on behalf of patients in the clinic and community-at-large. The qualified social worker will not be responsible for clerical tasks related to transportation, transient arrangements, insurance or billing, but will supervise the case aide who is responsible for these tasks. ***Rationale & References***: Clinical social work training is essential to offer counseling to patients for complex psychosocial issues related to ESRD and its treatment regimes. Changing the language of this definition will make the definition congruent to that of a qualified social worker that is recommended by CNSW for the transplant conditions of coverage. CNSW supports the elimination of the "grandfather" clause of the previous conditions of coverage, which exempted individuals hired prior to the effective date of the existing regulations (September 1, 1976) from the social work master's degree requirement. As discussed in the preamble for these conditions, we recognize the importance of the professional social worker, and we believe there is a need for the requirement that the social worker have a master's degree.

We agree that since the extension of Medicare coverage to individuals with ESRD, the ESRD patient population has become increasingly more complex from both medical and psychosocial perspectives. In order to meet the many and varied psychosocial needs of this patient population, we agree that qualified master's degree social workers (MSW) trained to function autonomously are essential. We agree that these social workers must have knowledge of individual behavior, family dynamics, and the psychosocial impact of chronic illness and treatment on the patient and family. This is why we argue that a specialization in clinical practice must be maintained in the definition.

Master's level social workers are trained to think critically, analyze problems, and intervene within areas of need that are essential for optimal patient functioning, and to help facilitate congruity between individuals and resources in the environment, demands and opportunities (Coulton, 1979; McKinley & Callahan, 1998; Morrow-Howell, 1992; Wallace, Goldberg, & Slaby, 1984). Social workers have an expertise of combining social context and utilizing community resource information along with knowledge of personality dynamics. The master of social work degree (MSW) requires two years of coursework and an additional 900 hours of supervised agency experience beyond what a baccalaureate of social work degree requires. An MSW curriculum is the only curriculum, which offers additional specialization in the biopsychosocialcultural, person-in-environment model of understanding human behavior. An undergraduate degree in social work or other mental health credentials (masters in counseling, sociology, psychology or doctorate in psychology, etc.) do not offer this specialized and comprehensive training in bio-psycho-social assessment and interaction between individual and the social system that is essential in dialysis programs. The National Association of Social Workers Standards of Classification considers the baccalaureate degree as a basic level of practice (Bonner & Greenspan, 1989; National Association of Social Workers, 1981). Under these same standards, the Masters of Social Work degree is considered a specialized level of professional practice and requires a demonstration of skill or competency in performance (Anderson, 1986). masters-prepared social workers are trained in conducting empirical evaluations of their own practice interventions (Council on Social Work Education). Empirically, the training of a masters-prepared social worker appears to be the best predictor of overall performance, particularly in the areas of psychological counseling, casework and case management (Booz & Hamilton, Inc., 1987; Dhooper, Royse & Wolfe, 1990). The additional 900 hours of supervised and specialized clinical training in an agency prepares the MSW to work autonomously in the dialysis setting, where supervision and peer support is not readily available. This additional training in the biopsychosocial model of understanding human behavior also enables the masters-prepared social worker to provide cost-effective interventions such as assessment, education, individual, family and group therapy and to independently monitor the outcomes of these interventions to ensure their effectiveness.

The chronicity of end stage renal disease and the intrusiveness of required treatment provide renal patients with multiple psychosocial stressors including: cognitive losses, social isolation, bereavement, coping with chronic illness, concern about worsening health and death, depression, anxiety, hostility, psycho-organic disorders, somatic symptoms, lifestyle, economic pressures, insurance and prescription

	issues, employment and rehabilitation barriers, mood changes, body image issues, concerns about pain, numerous losses (income, financial security, health, libido, strength, independence, mobility, schedule flexibility, sleep, appetite, freedom with diet and fluid), social role disturbance (familial, social, vocational), dependency issues, and diminished quality of life (DeOreo, 1997; Gudes, 1995; Katon & Schulberg, 1997; Kimmel et al., 2000; Levenson, 1991; Rabin, 1983; Rosen, 1999; Vourlekis & Rivera-Mizzoni, 1997). The gravity of these psychosocial factors necessitates an assessment and interventions conducted by a qualified social worker as outlined above. It is clear that social work intervention can maximize patient outcomes: • Through patient education and other interventions, nephrology social workers are successful in improving patient's adherence to the ESRD treatment regime. Auslander and Buchs (2002), and Root (2005) have shown that social work counseling and education led to reduced fluid weight gains in patients. Johnstone and Halshaw (2003) found in their experimental study that social work education and encouragement were associated with a 47% improvement in fluid restriction adherence. • Beder and colleagues (2003) conducted an experimental research study to determine the effect of cognitive behavioral social work services. They found that patient education and counseling by nephrology social workers was significantly associated with increased medication compliance. This study also determined that such interventions improved patients' blood pressure. Sikon (2000) discovered that social work counseling can reduce patients' anxiety level. Several researchers have determined that nephrology social work counseling significantly improves ESRD patient quality of life (Chang, Winsett, Gaber & Hathaway, 2004; Frank, Auslander & Weissgarten, 2003; Johnstone, 2003). Nephrology social work interventions also tend to be valued by patients. Siegal, Witten, and Lundin's 1994 survey of ESRD patients found that 90% of respondents "believed that access to a nephrology social worker was important" (p.33) and that patients relied on nephrology social workers to assist them with coping, adjustment, and rehabilitation. Dialysis patients have ranked a "helpful social worker" as being more important to them than nephrologists or nurses (Rubin, et al., 1997). In a study by Holley, Barrington, Kohn and Hayes (1991), 70% of patients said that social workers gave the most useful information about treatment modalities compared to nurses and physicians. These researchers also found that patients thought that social workers were twice as helpful as nephrologists in helping them to choose between hemodialysis and peritoneal dialysis for treatment.
494.140 Condition Personnel qualifications	***Add***: (e) Standard: Case aide. Dialysis units that have more than 75 patients per full time social worker must employ a case aide who- As supervised by the unit social worker, performs clerical tasks involving admissions, transfers, billing, transportation arrangements, transient treatment paperwork and verifies insurance coverage. ***Rationale & References***: We agree with the preamble that dialysis patients need essential social services

including transportation, transient arrangements and billing/insurance issues. We also firmly agree with the preamble that these tasks should not be handled by the qualified social worker (unless the social worker has fewer than 75 patients per full time equivalent social worker), as caseloads higher than this prevent the MSW from participating fully with the interdisciplinary team so that optimal outcomes of care may be achieved. It is imperative that the conditions of coverage identify a new team member who can provide social service assistance-the preamble recommends that these clerical tasks should be done by someone other than the MSW, but does not specify who that person is-adding this section (e) will eliminate any ambiguity surrounding this issue, and ensure adherence to this recommendation across all settings. Tasks that are clerical in nature or involve admissions, billing, and determining insurance coverage prevent nephrology social workers from performing the clinical tasks central to their mission (Callahan, Witten & Johnstone, 1997). Russo (2002) found that all of the nephrology social workers that he surveyed felt that transportation was not an appropriate task for them, yet 53% of respondents were responsible for making transportation arrangements for patients. Russo found that 46% of the nephrology social workers in his survey were responsible for making dialysis transient arrangements (which involved copying and sending patient records to out-of-town units), yet only 20% were able to do patient education. In the Promoting Excellence in End-of-Life Care's 2002 report, End-Stage Renal Disease Workgroup Recommendations to the Field, workgroup members recommended that dialysis units discontinue using master's level social workers for clerical tasks to ensure that they will have sufficient time to provide clinical services to their patients and their families. Merighi and Ehlebracht (2004b; 2004c; 2005), in a survey of 809 randomly sampled dialysis social workers in the United States, found that:

- 94% of social workers did clerical tasks, and that 87% of those respondents considered these tasks to be outside the scope of their social work training.
- 61% of social workers were solely responsible for arranging patient transportation.
- 57% of social workers were responsible for making travel arrangements for patients who were transient, taking 9% of their time.
- 26% of social workers were responsible for initial insurance verification.
- 43% of social workers tracked Medicare coordination periods.
- 44% of social workers were primarily responsible for completing admission packets.
- 18% of social workers were involved in collecting fees from patients. Respondents noted that this could significantly diminish therapeutic relationships and decrease trust.
- Respondents spent 38% of their time on insurance, billing and clerical tasks vs. 25% of their time spent counseling and assessing patients.
- Only 34% of the social workers thought that they had enough time to sufficiently address patient psychosocial needs.

This evidence clearly demonstrates that there needs to be another team member who can handle these clerical social service needs. This position would be cost-effective, as the person in this role can help

	patients obtain insurance coverage for dialysis that they normally would not have and increase facility's reimbursement. As discussed and referenced below in detail, CNSW recommends a ratio of 75 patients per full-time equivalent social worker. If a dialysis clinic has fewer patients per full-time equivalent social worker than less than 75:1, the social worker can address concrete social service needs of patients. However, patient ratios over 75 patients per full-time equivalent social worker require a case aide.
§494.180 Condition Governance. (b1) Standard. Adequate number of qualified and trained staff.	***Add***: (1i) No dialysis clinic should have more than 75 patients per one full time social worker. ***Rationale & References***: A specific social worker-patient ratio must be included in the conditions of coverage. Currently, there are no such national ratios and as a result social workers have caseloads as high as more than 300 patients per social worker in multiple, geographically separated, clinics. This is highly variable among different dialysis units-letting dialysis clinics establish their own ratios will leave ESRD care in the same situation as we have now with very high social work caseloads. For many years, CNSW has had an acuity-based social work-patient ratio (contact the National Kidney Foundation for the formula) which has been widely distributed to all dialysis units. This has largely been ignored by dialysis providers, who routinely have patient-to-social work ratios of 125-300. The new conditions of coverage must either identify an acuity-based social work staffing ratio model to be used in all units (we would recommend CNSW's staffing ratio), or set a national patient-social worker ratio. Leaving units to their own devices regarding ratios will not affect any change, as is evidenced by today's large caseloads and variability in such. CNSW has determined that 75:1 is the ideal ratio. If CMS refuses to include language about social work ratios, we strongly urge that the final conditions include language for "an acuity-based social work staffing plan developed by the dialysis clinic social worker" (rather than having nursing personnel who have limited understanding of social work training or role to determine social work staffing). Large nephrology social work caseloads have been linked to decreased patient satisfaction and poor patient rehabilitation outcomes (Callahan, Moncrief, Wittman & Maceda, 1998). It is also the case that social workers report that high caseloads prevent them from providing adequate clinical services in dialysis, most notably counseling (Merighi, & Ehlebracht, 2002, 2005). In Merighi and Ehlebracht's (2004a) survey of 809 randomly sampled dialysis social workers in the United States, they found that only 13% of full time dialysis social workers had caseloads of 75 or fewer, 40% had caseloads of 76-100 patients, and 47% had caseloads of more than 100 patients. In a recent study by Bogatz, Colasanto, and Sweeney (2005), nephrology social workers reported that large caseloads hindered their ability to provide clinical interventions. Social work respondents in this study reported caseloads as high as 170 patients and 72% of had a median caseload of 125 patients. The researchers found that 68% of social workers did not have enough time to do casework or counseling, tasks mandated by the current conditions of coverage, 62% did not have enough time to do patient education, and 36% said that they spent excessive time doing clerical, insurance, and billing tasks. One participant in their study stated: 'the combination of a more complex caseload and greater number of patients to cover make it impossible to adhere to the federal guidelines as written. I believe our patients

	are being denied access to quality social work services' (p.59). Patient-social work ratios are critical so that social workers can effectively intervene with patients and enhance their outcomes. It is clear that social work intervention can maximize patient outcomes (doing these requires reasonable ratios): • Through patient education and other interventions, nephrology social workers are successful in improving patient's adherence to the ESRD treatment regime. Auslander and Buchs (2002), and Root (2005) have shown that social work counseling and education led to reduced fluid weight gains in patients. Johnstone and Halshaw (2003) found in their experimental study that social work education and encouragement were associated with a 47% improvement in fluid restriction adherence. • Beder and colleagues (2003) conducted an experimental research study to determine the effect of cognitive behavioral social work services. They found that patient education and counseling by nephrology social workers was significantly associated with increased medication compliance. This study also determined that such interventions improved patients' blood pressure. Sikon (2000) discovered that social work counseling can reduce patients' anxiety level. Several researchers have determined that nephrology social work counseling significantly improves ESRD patient quality of life (Chang, Winsett, Gaber & Hathaway, 2004; Frank, Auslander & Weissgarten, 2003; Johnstone, 2003). A study currently being conducted by Cabness shows that social work intervention is related to lower depression. Nephrology social work interventions also tend to be valued by patients. Siegal, Witten, and Lundin's 1994 survey of ESRD patients found that 90% of respondents "believed that access to a nephrology social worker was important" (p.33) and that patients relied on nephrology social workers to assist them with coping, adjustment, and rehabilitation. Dialysis patients have ranked a "helpful social worker" as being more important to them than nephrologists or nurses by Rubin, et al. (1997). In a study by Holley, Barrington, Kohn and Hayes (1991), 70% of patients said that social workers gave the most useful information about treatment modalities compared to nurses and physicians. These researchers also found that patients thought that social workers were twice as helpful as nephrologists in helping them to choose between hemodialysis and peritoneal dialysis for treatment.
§494.180 Condition Governance. (b4) Standard. Adequate number of qualified and trained staff.	***Comment:*** CNSW agrees that all employees must have an opportunity for continuing education and related development activities.
§494.180 Condition Governance. (b5) Standard.	***Add (5ix):*** Add "Psychosocial issues related to ESRD and its treatment regimes, as provided by the facility social worker." ***Comment:*** Technicians have the most contact with patients and need to be attuned to patients'

Adequate number of qualified and trained staff.	psychosocial issues so as to most effectively collaborate with the social worker and achieve patient outcomes.
§494.180 Condition Governance. (h) Standard: Furnishing data and information for ESRD program administration.	(h) Standard: Furnishing data and information for ESRD program administration. ***Add***: (3)(new iv) "Annual reporting of facility aggregate functioning and well-being (physical component summary scores and mental component summary scores) and vocational rehabilitation status according to categories on the CMS 2728 form." ***Rationale***: These data would be easy to collect, would permit comparisons between clinics, and would serve as a basis for QAPI.

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04/28/2005

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention:CMS-3818-P
P.O. Box 8012
Baltimore, MD 21244-8012

To Whom It May Concern,

Enclosed are comments written by members of the Council of Nephrology Social Workers. As a member of the CNSW, I strongly support these recommended changes to the proposed Conditions for Coverage.

In addition, I have also typed a second list of suggestions that I would like to see reviewed during the comment period. I work as a member of an ESRD Network, and feel that the additional suggestions would reduce patient complaints and facility concerns regarding the care that is received in dialysis facilities across the country.

Thank you for allowing me the opportunity to submit these comments.

Melissa O'Neal, CSW

Subpart B – PATIENT SAFETY

§494.30 Condition: Infection Control
(a) Standard: Procedures for infection control
(1) We support using the Centers for Disease Control recommendations for infection control.

§494.60 Condition: Physical environment
We support the requirements of this section.

(c) Standard: Patient care environment
(2)(i) We support the requirement to keep the facility at a temperature comfortable for the majority of the patients.

(d) Standard: Emergency Preparedness
(3) We support the need for defibrillators in the dialysis facility.

We recommend that the current regulation at 405.2140 (b)(3) be retained "There is a nursing/monitoring station from which adequate surveillance of patients receiving dialysis services can be made."

Subpart C – PATIENT CARE

§494.70 Condition: Patients' rights
(a) Standard: Patients' rights
We support all of the patients' rights included in this section.

We recommend the addition of a patient's right to perform self care dialysis after successful completion of a training program.

(2) In addition to the patient receiving information in a way he/she can understand, we recommend retaining language from the current regulations at 405.2138 (c) "Provision is made for translators where a significant number of patients exhibit language barriers."

(5) We recommend that this be reworded to state the patient must "be educated on advance directives" rather than just "informed". We also recommend the patient has a right for their advance directives to be honored by the facility.

(b) Standard: Right to be informed regarding the facility's discharge and transfer policies
(1) We recommend the patient be informed of the facility discharge policies within 30 days of admission to the clinic.

(c) Standard: Posting of Rights
We support posting the phone numbers for the Network and State agency.

§494.80 Condition: Patient Assessment

(a) Standard: Assessment criteria
We support the assessment criteria, especially vascular access type and maintenance, vocational rehabilitation status and modality selection. We recommend adding language that would allow the Secretary to modify or update the criteria as new technology and knowledge become available.

(b) Standard: Frequency of assessment for new patients.

(1) We suggest the initial assessment be completed within 30 calendar days rather than 20 and that this regulation specify "first dialysis treatment at the dialysis facility" so it is not confused with the patient's first treatment in the hospital or other dialysis facility.

(d) Standard: Patient reassessment
(2) We support the definition of unstable patient and the need to assess unstable patients monthly.

§494.90 Condition: Patient plan of care
We suggest "The interdisciplinary team" be defined in the same way it is at 494.80 "...consisting of, at a minimum, the patient (if the patient chooses) or the patient's designee, a registered nurse, a nephrologist or the physician treating the patient for ESRD, a social worker, and a dietitian..."

We also recommend that a patient's refusal to participate in the care plan be documented in the plan of care.

(a) Standard: Development of patient plan of care

We recommend that the patient's advance directives be included in the patient plan of care.

(4) We support the vascular access assessment and suggest it be strengthened by adding a requirement that for any patients not dialyzing via a fistula the plan document the reasons a fistula is not being used and a plan for fistula placement for eligible patients.

(6) We recommend that Functional Status be included as part of the rehabilitation section of the patient care plan.

(b) Standard: Implementation of the patient plan of care
(1) We recommend the patient plan of care be signed by the patient's attending physician.

(c) Standard: Transplantation referral tracking
We support the requirements for transplantation referral tracking.

§494.100 Condition: Care at Home

We recommend that this section be modified to address patients performing self care dialysis in the dialysis facility or that a separate section be added. The conditions need to address policies and procedures for self care in the facility, staff and patient training and a clear definition of self care dialysis.

(c) Standard: Support Services
(1)(i) We suggest "periodic monitoring" be modified to say "at least annually".

§494.110 Condition: Quality assessment and performance improvement
We support the requirements for a facility QI program.

(a) Standard: Program scope
We recommend the addition of patient satisfaction as one of the measures.

Subpart D-ADMINISTRATION

§494.140 Condition: Personnel qualifications
(a) Standard: Medical Director
(1) We recommend the Medical Director needs to be Board eligible.

(d) Standard: Social worker
We support the requirement for the social worker to hold a master's degree in social work.

(e) Standard: Patient care dialysis technicians
We support specific requirements for dialysis technicians.

(3) We recommend that the requirement for technicians to receive training in "communication and interpersonal skills including patient sensitivity training and care of difficult patients" be required at least annually and that it be required for all patient care staff, not just technicians.

§494.150 Condition: Responsibilities of the medical director
We support the revised language for medical director responsibilities, especially (c)(2)(i) requiring the medical director to ensure all policies and procedures are adhered to by all individuals who treat patients in the facility. We recommend the medical director be given the ability and authority to monitor and improve the care provided by attending nephrologists.

We recommend that dialysis facilities appoint only one Medical Director at any given time to avoid confusion as to who is responsible. We currently have 81 facilities who report having more than one Medical Director. 44 with two Medical Directors, 18 with three Medical Directors, 5 with four Medical Directors, 9 with five Medical Directors, 2 with six Medical Directors, 3 with seven Medical Directors on record.

We recommend that the Medical Director be responsible for ensuring the facility complies with the goals of and acts upon recommendations from the ESRD Network.

§494.160 Condition: Relationship with the ESRD Network
We recommend that "statement of work" be replaced with "goals and objectives" to be consistent with the legislation and that the language in the current regulations §405.2134 "participate in network activities" be retained.

§494.170 Condition: Medical Records
(c) Standard: Record retention and preservation
We recommend the regulation specify what information must be kept in the active patient's chart, readily available. §405.2139 of the current regulation provides language: "(a) Standard: medical record. Each patient's medical record contains sufficient information to identify the patient clearly, to justify the diagnosis and treatment, and to document the results accurately. All medical records contain the following general categories of information: Documented evidence of assessment of the needs of the patient, whether the patient is treated with a reprocessed hemodialyzer, of establishment of an appropriate plan of treatment, and of the care and services provided (see Sec. 405.2137(a) and (b)); evidence that the patient was informed of the results of the assessment described in Sec. 405.2138(a)(5); identification and social data; signed consent forms referral information with authentication of diagnosis; medical and nursing history of patient; report(s) of physician examination(s); diagnostic and therapeutic orders; observations, and progress notes; reports of treatments and clinical findings; reports of laboratory and other diagnostic tests and procedures; and discharge summary including final diagnosis and prognosis."

§494.180 Condition: Governance
We recommend retaining the language from the current regulations, §405.2136 Condition: Governing body and management, (d) Standard: personnel policies and procedures and (f)(3) of that section "The facility policy provides that, whenever feasible, hours for dialysis are scheduled for patient convenience and that arrangements are made to accommodate employed patients who wish to be dialyzed during their non-working hours and (g) of that section Standard: medical supervision and emergency coverage.

(b) Standard: Adequate number of qualified and trained staff
(1) We recommend that "adequate number of qualified personnel" be replaced with staffing ratios, using the recommendations to the professional organizations if available – Nurses – 1:10, Direct patient care staff 1:4, Social workers 1:75, Dietitians 1:125.

(2) We support the requirement that a registered nurse be present at all times. We recommend this language be clarified to state the registered nurse must be in the immediate clinical care area, not just in the building.

(4) We suggest this language be modified to "All employees are provided continuing education and related development activities"

(5) We recommend that the training program cover each of the required topics at least annually.

(5) We recommend that (ii) Care of patients with kidney failure, including interpersonal skills be expanded to include communication and sensitivity training and that it be required for all staff, not just dialysis technicians.

We recommend that all staff be trained on the principles of Quality Improvement and quality standards and on the role of the ESRD Network.

(c) Standard: Medical staff appointments
We recommend that the governing body authorize and require the medical director to monitor and improve the performance of all attending nephrologists in the facility.

(f) Standard: Discharge and transfer policies and procedures
(4) We support the reassessment of the patient prior to discharge.

(4)(ii) We support the requirement that medical director and attending physician must sign the discharge orders.

(4)(iv) We support the requirement that the dialysis facilities notify the ESRD Network of involuntary discharges and transfers. We suggest this be modified to require facilities to notify the Network prior to the discharge unless it involves an immediate threat to the health and safety of others, in which case the facility should notify the Network within 48 hours of the discharge.

74

ORIGINAL

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April 30, 2005

Centers for Medicare & Medicaid Services
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Attention: CMS-3818-P
PO Box 8012
Baltimore, MD 21244-8012

To Whom It May Concern:

I am a nephrology social worker and am writing in response to the proposed Dialysis Conditions of Coverage. I support the position of the Council of Nephrology Social Workers and in addition make the following comments:

494.70 Condition Patients' Rights (a) Standard: Patients' Rights

I strongly believe in the importance of Advance Directives and of a qualified social worker being involved in educating patients regarding their rights in this area. Currently, my company (one of the top five) has directed that social workers *not* be involved in helping patients complete Advance Directives. We need CMS to provide clear guidelines and support of our professional expertise.
References: Bartlow, 2005; CNSW, 2002; Yuscak, 1999

Comment & Addition to a6, CNSW is recommending Add: (new 26) "Receive counseling from a qualified social worker to address concerns related to the patient's adjustment to illness, including changes to life-style and relationships because of his illness, developmental issues affected by his illness, and any behavior that negatively affects his health or standing in the facility."

Again, I can't stress enough the importance of CMS recognizing and directing that Master's level social workers use their training to intervene with patients to facilitate optimal patient functioning and adjustment.
References: McKinley & Callahan, 1998; Vourlekis & Rivera-Mizzoni, 1997

494.80 Condition Patient Assessment (a) Standard: Assessment Criteria
I urge the change CNSW specifies for (a7) for two reasons. First is the importance of national coherence. Secondly, CMS must specify the role of the qualified social worker in assessing and addressing psychosocial issues to give guidance to employers. We have already seen under the current COC's how employers have used the lack of clarity in the language to assign social workers numerous clerical tasks that are well outside the parameters of our profession.
References: Callahan, Witten & Johnstone, 1997; Russo, 2002; Promoting Excellence in End-of-Life Care 2002 report, End-Stage Renal Disease Workgroup Recommendations to the Field; Merighi & Eclebracht (2004b, 2004c, 2005)

494.80 Condition Patient Assessment (b) Standard: Frequency of assessment for new patients (1) and (2). I agree that the initial assessment and care plan should be combined and conducted within 30 calendar days after the first dialysis treatment. A follow-up assessment and care plan within 90 days for new patients is excessive and not always necessary. Standard reassessment guidelines as outlined below should be followed so that any patient who meets the criteria of "unstable" will be reassessed whether or not they are new, within the three months, etc. With current caseloads and clerical tasks in a large unit with high activity, ie. multiple admissions and discharges, the 90 day reassessment requirement will translate into large amounts of time spent completing paperwork to ensure compliance with this requirement. However, if both the case aide requirement and the caseload ratio are added (see below), then the qualified social worker should have ample time to complete these assessments and provide the interventions necessary to enable patients to achieve optimal quality of life on dialysis.
References: Callahan, Witten & Johnstone, 1997; Russo, 2002; Promoting Excellence in End-of-Life Care 2002 report, End-Stage Renal Disease Workgroup Recommendations to the Field; Merighi & Eclebracht (2004b, 2004c, 2005)

494.80 Condition Patient Assessment (d) Standard: Patient Reassessment
With the change to 494.80 (a7) recommended by CNSW, psychosocial needs will be clearly defined and ensure national coherence on the exact psychosocial needs that require reassessment. At least annually is adequate for stable patients. Other patients who present a psychosocial need after the initial assessment can be reassessed at the time of presentation instead of an arbitrary time frame such as 90 days after initial start.

494.140 Condition Personnel Qualifacations (d) Standard: Social Worker
I can not improve on CNSW's response to this section or more eloquently state the importance of *clearly defining and monitoring* the responsibilities assigned to the qualified social worker. Dialysis providers can not be depended upon to use qualified social workers for only professionally appropriate tasks unless CMS and other regulatory agencies are routinely surveying for compliance in this area. Social work intervention can and does maximize patient outcomes when it is allowed to occur. It is also valued and appreciated by patients because they recognize that social work intervention makes a difference in the quality of their lives.
References: Auslander & Buchs, 2002; Root, 2005; Johnstone & Halshaw, 2003; Beder et al, 2003; Chang et al, 2004; Frank et al, 2003; Johnstone, 2003; Rubin et al, 1997, Holley et al, 1991; Callahan, et al, 1998

494.140 Condition Personnel Qualifications Add: (3) Standard: Case Aide
The addition of a case aide in units serving 75 patients or more is long overdue. Under the qualified social worker's supervision, a case aide can perform clerical tasks for admissions, travel and transients, transportation, billing and insurance. These tasks are currently performed by 94% of social workers (Merighi & Ehlebracht, 2004b; 2004c; 2005). The same studies indicated that only 34% of social workers thought that they had enough time to sufficiently address patient psychosocial needs. Clerical tasks are extremely time-consuming and take away from the time available to the social worker to spend time with patients addressing psychosocial needs. It is also a conflict of interest to the therapeutic relationship to have the social worker involved in billing/insurance issues simultaneously addressing clinical issues.
References: Bogatz, 2000; Callahan, Witten & Johnstone, 1997; Russo, 2002; Promoting Excellence in End-of-Life Care 2002 report, End-Stage Renal Disease Workgroup Recommendations to the Field; Merighi & Eclebracht (2004b, 2004c, 2005)

494.180 Condition Governance (b1) Standard: Adequate number of qualified and trained staff Add: (1l) No dialysis clinic should have more than 75 patients per one full-time social worker.
There are no national ratios for social work caseloads. Therefore, the caseload numbers vary alarmingly. CMS needs to address caseload ratios or at least identify an "acuity-based social work staffing plan developed by the dialysis clinic social worker." The nurse manager or facility administrator has limited understanding and training to determine social work staffing.
References: Callahan, et al, 1998; Merighi & Ehlebracht, 2004a; Bogatz, et al, 2005; Auslander & Buchs, 2002; Root, 2005; Beder, et al, 2003; Sikon, 2000; Callahn et al 1997.

Respectfully Submitted,

Camille M. Yuscak, LCSW-R, ACSW, LCSW
Licensed Clinical Social Worker-R, New York
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Academy of Certified Social Workers, National Association of Social Worker

References

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PENINSULA NEPHROLOGY

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30 April 2005

TO: Centers for Medicare and Medicaid Services
Department of Health and Human Services
ATTENTION: C M S – 3818-P
P O Box 8012
Baltimore, MD 21244-8012

RE: Facilities File Code C M S – 3818-P. Conditions for Coverage for End Stage Renal Disease.

SUBJECT: Comments in response to Facilities File Code C M S – 3818-P.

The following responses are being submitted to the sections indicated:

494.10 Definitions. Dialysis Facility, New Staff, Assisted Skilled Nursing, Home Dialysis.

494.20 Condition. Compliance with Federal, State, local laws and regulations

494.60 Condition. Physical Environment. c) Patient Care Environment

494.70 Condition. Patient's Rights. a) Standard Patients' Rights.
Condition. Patient's Rights. b) Standard: Right to be informed regarding the Facility's Discharge and Transfer Policies.

494.80 Condition. Patient Assessment. a) Standard Assessment Criteria.
Condition. Patient Assessment. b) Standard. Frequency of Assessment for New Patients.
Condition. Patient Assessment. d) Standard Patient Reassessment.

494.90 Condition. Patient Plan of Care. a) Standard Development of Patient Plan of Care.
Condition. Patient Plan of Care. b) Standard: Implementation of Patient Plan of Care.
Condition. Patient Plan of Care. d) Standard: Patient Education and Training.

494.140 Condition. Personnel Qualifications d) Standard: Social Worker.

494.180 Condition. Governance. (b4) Standard: Adequate number of qualified and trained staff.

I have been employed as a Renal Social Worker for more than 23 years. Twenty of these years were with a Hospital dialysis program, where I worked with the acute, hemodialysis and peritoneal dialysis patients. I am currently employed with a private dialysis center, where I am assigned to the hemodialysis division.

Sincerely,

Shirley T. Cook, M. S. W.

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May 2, 2005

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-3818-P
P.O. Box 8012
Baltimore, MD 21244-8012

To Whom It May Concern:

Thank you for the opportunity to comment on the *Conditions for Coverage of End-Stage Renal Disease Facilities.* As a social worker, I commend CMS for drafting such patient-centered Conditions. I also appreciate the focus on rehabilitation and the clinical social work role in achieving positive rehabilitation outcomes. There are those in the renal community who believe that the only responsibility a dialysis clinic has is to clean patients' blood. They discount patients, devalue social workers, and discredit rehabilitation as an expensive unfunded mandate. I disagree.

Although my comments are lengthy, my main points are:

- **All patients—urban, suburban, and rural--deserve to have access to a clinical MSW who has the time and administrative support to provide the clinical services that can help them and their families cope with kidney disease and achieve their goals.** I commend CMS for deleting the grandfather clause. *Twenty-nine years is long enough to get an MSW.*
- **CMS should require regular assessment of functioning and well-being (FWB) and add monitoring of FWB as a QAPI.** Experts recommended specific surveys to measure FWB. The SF-36 and variants and the KDQOL have been used most frequently in dialysis. They yield physical component summary (PCS) and mental component summary (MCS) scores. Research has shown PCS and MCS scores are predictive of *hospitalizations and death,* and that exercise and counseling improve scores which, in turn, improve outcomes.
- **CMS should add monitoring of vocational status as a QAPI.** Helping patients keep their jobs benefits patients and families, dialysis clinics, and society. Home dialysis and transplant are the most work-friendly treatments. Yet 91% of patients choose in-center dialysis—many because they were not informed of options. Requiring staff to tell patients about all treatments and where to find them should increase home dialysis use and help more patients work.

Sincerely,

Beth Witten

Beth Witten, MSW, ACSW, LSCSW

April 29, 2005

Centers for Medicare & Medicaid Services,

Department of Health and Human Services,

Attention: CMS–3818–P,

PO Box 8012,

Baltimore, MD 21244–8012.

Dear CMS,

Thank you for all of your hard work on updating these guidelines.

Attached you will find my opinions and feedback on the proposed regulations.

In addition I would like to add and reinforce the following in regards to Social Work Services – **"Personnel Qualifications"**

I agree with your following statements from the Federal Register and would like to see inclusion of them in the regulations themselves:

4. Social Worker (Proposed §494.140(d))

"We recognize that dialysis patients also need other essential services including transportation and information on Medicare benefits, eligibility for Medicaid, housing, and medications, but these tasks should be handled by other facility staff in order for the MSW to

participate fully with the patient's interdisciplinary teams so that optimal outcomes of care may be achieved."

I would ADD that it is inappropriate as well, and obstructional to federal guidelines goals when the social worker is used as an admissions clerk(filling in papers, copying them, filing them), a travel agent(telephone calls to and with facilities on paperwork issues), an insurance broker(copying insurance cards, getting updated insurance information, collecting their insurance premium bill), and accountant (taking full financial statements from our patients, collecting their tax returns, bank statements, paystubs, collecting their expenses, collecting their copayments).

Your description below is what the Social Worker should be used for, not these clerical duties that compromise our therapeutic relationship with our patients that then makes it very difficult, and in some cases impossible, to provide therapeutic services to optimize outcomes.

4. Social Worker (Proposed §494.140(d))

"ESRD is an extremely complex disease requiring highly technical and complex treatment, and patients with this disease have special needs that require highly specialized care that can only be provided by qualified personnel. As the demographics of the dialysis population continue to change, producing a more elderly patient population with more co-morbid conditions, direct patient care needs and the skill needed to meet those needs will continue to increase. Also, as we move

away from unnecessary process and procedural requirements in the conditions for coverage towards better patient outcomes, it becomes even more important to have qualified, experienced, and well-trained staff to achieve the targeted clinical outcomes for each patient. "

4. Social Worker (Proposed §494.140(d))

"We recognize the importance of the professional social worker, and we believe there is a need for the requirement that the social worker have a master's degree. Since the extension of Medicare coverage to individuals with ESRD, the ESRD patient population has become increasingly more complex from both medical and psychosocial perspectives. In order to meet the many and varied psychosocial needs of this patient population, we believe qualified master's degree social workers (MSW) trained to function autonomously are essential. Social workers must have knowledge of individual behavior, family dynamics, and the psychosocial impact of chronic illness and treatment on the patient and family. The dialysis patient needs psychosocial evaluations, a treatment plan based on the patient's current psychosocial needs, and direct social work interventions. Facility social worker services include counseling services, long-term behavioral and adaptation therapy, and grieving therapy. We believe that MSW training provides the necessary education and experience in these areas. "

"While nonprofessional personnel may serve in a supportive capacity, we do not believe they can be employed in place of a fully-credentialed MSW."

---

4. Social Worker (Proposed §494.140(d))

I disagree with the following proposal:

"We have removed the requirement for specialization in clinical practice, because this designation is not available in all States and may prove to be a barrier to social workers entering practice in the dialysis arena."

Because of the professional duties described above as well as others described in the attached opinions, I think it would be a detriment to the successful provision of professional Social Work services to eliminate the clinical specialization requirement. In most instances appropriate schooling is available. I would recommend a subcommittee or task force to be delegated with how to problem solve in the few states where the specialization is not at all available. I would recommend that facilities/administrators that are having hiring difficulties get the benefit of consultation with State representative of CMS to offer assistance in exhausting all possibilities for finding appropriate candidates. It may be that in some cases the facilities need to recontour their job offers to make their positions desirable to qualified candidates i.e. lower the patient caseload, don't have the social worker cover multiple units, offer

caseaids, etc. It is reasons like this, in some cases, that facilities are not able to draw qualified candidates, NOT because there is NO appropriate schooling available....there just may be LESS availability.

I also recommend dropping the use of term "social services". With the acknowledgement of the social work profession, it would be appropriate to change the term to "social work services". "Social Services" are workers, not necessarily degreed workers even, who provide foodstamps, housing vouchers, and welfare check services. "Social Work Services" is a more accurate description of the Master's Level Social Worker and more respectful.

Once again, I would like to thank you for all your time and efforts put forth in these proposed regulations and I would like to thank you in advance for the all the time and hard work you will put into finalizing the Conditions For Coverage for dialysis clinics.

Sincerely,

Chris Sarfaty MSW, LICSW
SNE CQI Lead Social Worker
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May 2, 2005

Centers For Medicare and Medicaid Services
Department for Health and Human Services
Attention: CMS-3818-P
POBox 8012
Baltimore, MD 21244-8012

Please note the attached comments regarding the Conditions of Coverage for Dialysis.

I am a social worker with 22 years experience in renal replacement therapies. I am most interested to focus on the following conditions:

- 494.80 Condition: Patient Assessment
- 494.90 Condition: Patient Care of Plan
- 494.140 Condition: Personnel qualifications (d) Standard: Social Worker.

In addition: I recommend that personnel qualifications include personnel responsibilities. It is suggested that 494.150 be renamed Condition: Personnel Responsibilities and include a discussion of the responsibilities of each team member (instead of just the medical director as is currently proposed).

Sincerely,

Phyllis H. Leggett, MSW, LCSW
Social Worker
DCA-Vineland
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THOMAS LEPETICH
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May 1, 2005

Centers for Medicare and Medicaid Services
Attention: CMS - 3818 - P
P.O. Box 8012
Baltimore, Md 21244-8012

COMMENTS: CMS - 3818 - P
42 CFR Parts 400, 410, 412, 413, 414, 488 and 494
Medicare Program: Conditions for Coverage for End Stage Renal Disease Facilities

To Whom It May Concern:

Attached are my comments for the Medicare Program's Conditions for Coverage for End Stage Renal Disease Facilities. I have reviewed the comments by the Council of Nephrology Social Workers and agree with them fully. Therefore, I am submitting there comments as a representation of my own.

Sincerely,

Thomas Lepetich, MSW, LCSW

Thomas Lepetich, MSW, LCSW
Dialysis Social Worker
436 Valley Run Drive
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80

April 29, 2005

Centers for Medicare and Medicaid Services
Dept. of Health and Human Services
Attn: CMS-3818-P
PO Box 8012
Baltimore, MD 21244-8012

To Whom It May Concern:

Enclosed is an original and 2 copies of my comments on the proposed Conditions of Coverage for Dialysis Facilities.
I have been a dialysis social worker for 14 years and work in an urban center that treats approximately 230 kidney failure patients. I have been extensively involved with the work of the Renal Network (Region 9/10) and the national and local National Kidney Foundations.
Thank you for considering my comments.

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CALIFORNIA HOSPITAL ASSOCIATION
Providing Leadership in Health Policy and Advocacy

May 3, 2005

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-3818-P
P.O. Box 8012
Baltimore, MD 21244-8012

Re: CMS-3818-P; Medicare Program; Conditions for Coverage of End Stage Renal Disease Facilities; Proposed Rule

To Whom It May Concern:

The California Hospital Association (CHA) represents nearly 500 California hospitals and health systems. We appreciate the opportunity to comment on the proposed rule regarding conditions for coverage of end-stage renal disease (ESRD) facilities.

DIALYSIS OF ESRD PATIENTS IN SKILLED NURSING FACILITIES

CHA's primary concern relates to the provisions regarding dialysis in skilled nursing facilities (SNFs). More than one-third of California hospitals operate hospital-based SNFs. These facilities play an important role in helping all hospitals manage their patient population by caring for stable, yet medically fragile, patients. We are seeing an increasing number of patients who have complex medical needs and require dialysis, but are otherwise stable.

These patients could be cared for by nursing facilities. Because of current Medicare coverage interpretations, however, these patients often remain in the hospital intensive care unit (ICU) needlessly. We appreciate the Centers for Medicare & Medicaid Services' (CMS) recognition of this problem as acknowledged in the proposed rule. Allowing SNF residents to access home dialysis, however, does not solve the problem. We urge CMS to revise its position and make it financially feasible for nursing facility patients to receive dialysis at the bedside from a dialysis facility or a SNF.

DATA

CHA recently conducted a survey of its members to determine how nursing facilities are currently handling residents who require dialysis. Nearly 25 percent of California's 170 hospital-based SNFs responded to the survey. Of those responding, 40 percent had cared for a total of 266 patients who required dialysis over a one-year period. At the same time, an even greater number of patients were turned away by responding facilities because the patients required dialysis.

Of the dialysis patients who were admitted to SNFs, 50 percent had a length of stay of 14 days or less; 80 percent had a length of stay of 30 days or less; 90 percent were on dialysis prior to admission to the SNF and 86 percent continued to require dialysis upon discharge. About half of them suffered from ESRD.

In addition, 65 percent were 65 years and older; 92 percent were 50 years and older. More than 60 percent were on Medicare Part A stay in the SNF. Approximately 15 percent were dually eligible, and a mere 5 percent were insured by Medicaid only.

Approximately, 38 percent of these patients fell into resource utilization groups (RUGs) RHC and RHB; 17 percent fell into SE3 and SE2; 19 percent were evenly spread across RUB, RVB, RMC, RMB, and SSA.

Half of the patients were discharged to home; 20 percent were discharged to another SNF; and 20 percent were discharged to the hospital. *None of the patients received home dialysis.*

PROVISION OF HOME DIALYSIS TO SNF PATIENTS IS INAPPROPRIATE

Patients are Too Fragile for Home Dialysis

Nursing home patients who typically require dialysis are extremely fragile. The stability of their health status is precarious; it can change at a second's notice.

The home dialysis benefit, on the other hand, is designed for dialysis patients who are healthier and sturdier than the average dialysis patient. Home dialysis is supposed to be self-administered by the dialysis patient.

These nursing home residents, in contrast, often have difficultly simply sitting up in a dialysis chair for the duration of a treatment. They are in no condition to be engaged in, oversee, or in any way be responsible for their own dialysis treatment.

Dialysis is a complex medical procedure. It involves the cleansing of a person's blood, which is vital to every organ in the body. This process puts a person into disequilibrium. If that person's health is compromised in any other manner, the dialysis process can trigger complex systems failures that require sophisticated knowledge to reverse. Thus, home dialysis should be reserved only for patients whose health is not otherwise compromised.

Home Dialysis is Problematic for Short-Stay Patients

The proposed rule suggests that short-stay patients aren't eligible for home dialysis because the SNF is not their "home." While CHA believes that a SNF is at all times both a home *and* an institution for all residents – albeit temporary for some – we agree that home dialysis is impractical for short-stay patients.

The vast majority of nursing facility residents who require dialysis receive dialysis services both prior to and after their stay in the SNF. Their stay in the nursing facility is a short break – 30 days or less – in the midst of ongoing dialysis treatment. Rarely, if ever, are these patients on home dialysis prior to or after the SNF stay.

As a result, these patients who are typically on chronic dialysis would have to switch to home dialysis and back again to chronic dialysis within a very short and unrealistic time frame. The current system cannot support demands for such quick benefit coverage decisions. Thus, patients' continuity of care would be jeopardized.

Conclusion

For the above-stated reasons, use of home dialysis in nursing homes is inappropriate for the vast majority of nursing home residents.

BEDSIDE DIALYSIS SERVICES PROVIDED BY DIALYSIS FACILITY OR NURSING FACILITY SHOULD COVERED BY MEDICARE

Currently, the vast majority of nursing home patients requiring dialysis receive such services at an off-site dialysis clinic. This situation has significant drawbacks. First, it necessitates use of an ambulance – and Medicare resources – to transport the patient to and from the clinic. Second, being transported and sitting up in a dialysis chair are extremely taxing on residents whose health is already seriously compromised. Third, it requires the patient to be out of the nursing facility for a significant amount of time, which, as acknowledged in the proposed rule, increases the likelihood the patient will miss medication administration, treatment regimens, meals and planned activities. Fourth, because of the resident's medical fragility it is not uncommon for the resident to require accompaniment of a SNF nurse, which takes resources away from other SNF residents.

CHA believes that Medicare should cover dialysis provided at the bedside in the nursing facility when provided by a dialysis facility or the nursing facility. Doing so would create a win-win situation. Nursing facility residents requiring dialysis would receive better care. Medicare would save ambulance costs. And many hospitalized dialysis patients would move sooner from the hospital to a lower level of care, thus providing for more effective and efficient use of our nation's limited health care resources.

CHA urges CMS to investigate more thoroughly the possibility of the following options:

- The renal dialysis facility provides the services at the SNF and is paid the composite rate directly;
- The SNF provides the services and receives payment outside the prospective payment system (PPS) for Part A patients (i.e., services are exempt from consolidated billing); and
- The SNF provides the services, without separate ESRD licensure, for beneficiaries who have exhausted Part A (i.e., develop separate conditions of coverage requirements that would apply only to SNFs that already meet the SNF conditions of participation).

Not only does CHA believe these options are the right thing to do, we also believe that they are consistent with existing Medicare law. For residents on a Part A stay, the relevant provisions are Sections 1881(b)(1) and 1888(e)(2)(A)(i)(II).

> Section 1881(b)(1) states that "payments on behalf of such individuals [ESRD beneficiaries] to providers of services and renal dialysis facilities which meet such requirements as the Secretary shall by regulation prescribe for institutional dialysis services and supplies."

This references both providers of services, which SNFs are under the statute, and renal dialysis facilities. Thus, it appears that CMS is authorized to pay SNFs the composite rate under Part B. In addition, it seems that CMS has some flexibility under the statute to develop separate requirements for different provider types.

> Section 1888(e)(2)(A)(i)(II) stipulates that "covered skilled nursing facility services" include: "all items and services (other than items and services described in clause (ii) and (iii)) for which payment may be made under Part B and which are furnished to an individual who is a resident of a skilled nursing facility during the period in which the individual is provided covered post-hospital extended care services."

Dialysis services (at least those that are paid with a "composite rate" – a per-episode capitated amount) are considered Part B services and, since they are not "described in clause (ii) and (iii)," they are not carved out of the SNF PPS bundle.

For residents who are *not* on a Part A stay, the relevant provisions are Section 1861(s)(2)(F) and the "on the premises" requirement in the Code of Federal Regulation. Section 1861(s)(2)(F) – where dialysis is excluded from consolidated billing – references "institutional dialysis services," but does not define that term. Rather, the references lead back to Section 1881, which suggests through the separate mention of providers that SNFs could also be included in the regulatory definition.

Although federal regulation references the requirement that dialysis services be provided "on the premises" of the dialysis provider, this requirement does not appear in statute. Thus, CHA believes CMS has the flexibility to alter this requirement through regulation as well.

Conclusion

For the above-stated reasons, CHA urges Medicare to make it financially feasible for SNF residents to receive dialysis services at the SNF, whether under a Part A stay or Non-Part A stay and whether performed by a dialysis provider or by the SNF.

COMMENTS ON HOME DIALYSIS PROPOSED RULES

For the small number of nursing home residents who might be able to benefit from home dialysis, CHA has the following comments.

Nursing Coverage

The proposed rule would require that a registered nurse (RN) be on the premises whenever in-center patients are being treated. This requirement would take the place of the current requirement that a licensed health professional experienced in rendering ESRD be on duty. CHA supports this approach in the proposed rule. We believe that having an RN on the premises is appropriate with promoting good patient care in the nursing home setting.

Feedback was requested on whether CMS should address caregiver-to-patient ratios in the regulations. CHA strongly opposes, however, to a one-size-fits-all approach to caregiver coverage. The number of caregivers needed to promote quality care varies with the particular circumstances in any given setting, including, but not limited to, the physical configuration of the facility, the experience and skill level of the particular caregivers involved, and the specific health needs of the patients at issue. It is appropriate for CMS to provide guidance with respect to staffing, but minimum levels or thresholds are inappropriate.

Monitoring

The proposed regulations provide that the ESRD facility should be responsible for the ESRD services provided, including assessing staff competency, reviewing data, monitoring care, monitoring the impact on other nursing home residents, monitoring the premises, monitoring supplies and equipment, maintaining medical records, and assuring residents rights are respected.

CHA supports holding the ESRD provider responsible for matters related to the dialysis treatment. The ESRD provider is the one with the dialysis expertise. Thus, ESRD providers should be responsible for those matters within their expertise.

Competency

CMS also solicited input on the competency requirements that should be established for caregivers. CHA believes that competency training and testing should address problems that can surface both during and after a dialysis treatment. Since these patients are physically compromised, it is critical that caregivers know the signs, symptoms and treatment for complications that could arise during dialysis.

Patient Choice

CHA requests clarification on whether nursing facilities that have residents on home dialysis can limit the dialysis provider or the durable medical equipment (DME) provider the resident uses. Can the SNF prevent residents from opting Method II? Can the SNF limit the dialysis providers from which residents may choose? Can the SNF limit the patients' options to providers with which the nursing facility has a contractual relationship?

SUMMARY

The number of patients who require dialysis, but could otherwise be cared for in a nursing facility, are increasing. Home dialysis is inappropriate for the vast majority of nursing home residents because of their medical fragility. CHA urges CMS to interpret existing law in such manner as to make it financially feasible for SNF residents to receive dialysis services from dialysis providers or SNFs while at the bedside.

If you have any questions or comments, please contact Judy Citko at (916) 552-7573 or jcitko@calhealth.org.

Sincerely,

C. Duane Dauner
President

CDD/JC:nr

Desk 83

(attachment chart)

Teri Arthur, MSW, LSW
6022 S. Drexel Avenue
Chicago, IL 60637
773-368-6429
teri@uchicago.edu

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–3818–P
PO Box 8012
Baltimore, MD 21244–8012

April 26, 2005

Enclosed you will find my response to the proposed dialysis conditions of coverage (one original and two copies). I am also enclosing a CD with the response included in case it is easier to have an electronic version of my response. Thank you very much for your consideration of my comments, which stem from my 10 years of experience in dialysis facilities across the country and extensive participation in nephrology organizations.

Sincerely,

Teri Arthur

Teri Arthur, MSW, LSW

UMC HEALTH SYSTEM

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May 2, 2005

The Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-3818-P
P O Box 8012
Baltimore, MD 21244-8012

Re: CMS 3818 – P; Subpart D – Administration Section 494.140 Condition: Personnel

Gentlemen:

In particular, I wish to support the position of the Council of Nephrology Social Workers (CNSW) in regards to the language and qualifications of professionals who are assigned the responsibility of psychosocial assessment. Please change the language describing social workers to Master level social workers eliminating the qualifications allowing non-social workers to provide psychosocial assessments.

Professional social workers, educated at the Master's level, from Colleges and Universities credentialed by the Council of Social Work Education, have knowledge and expertise in dealing with the whole person. Our patients who suffer from End Stage Renal Disease have complex, multiple-disease driven issues that require trained individuals who are able to approach patients with an understanding of these unique challenges.

I am attaching one section of the CNSW comment that I feel is of significance. This attachment requests defining responsibilities to establish full professional services to renal patients.

Sincerely,

Evelina Martin LCSW MSSW

Evelina Martin, LCSW, MSSW
Clinical Social Worker
Kidney Transplant Program.

Attachment (5)

Comment: CNSW recommends that this section be renamed "Personnel qualifications and responsibilities", with the addition of specified personnel responsibilities to each team member's qualifications. If it is decided that adding "personnel responsibilities" to this section is inappropriate, we would suggest the alteration of 494.150 to be renamed "Condition: Personnel Responsibilities" and include a discussion of the responsibilities of each team member (instead of just the medical director as is currently proposed). CNSW suggests possible responsibilities for social workers in the next section, where we comment on "494.140 Condition Personnel qualifications (d) Standard: Social worker." These suggestions can be used in a new "responsibilities" section.

Rationale & References: It is critically important to clearly delineate personnel responsibilities in some fashion in these new conditions of coverage to ensure that there is parity in the provision of services to beneficiaries in every dialysis unit in the country. It is just as important to outline each team member's responsibilities as it is the medical director's, as is currently proposed. This is especially important regarding qualified social work responsibilities. Currently, many master's level social workers are given responsibilities and tasks that are clerical in nature and which prevent the MSW from participating fully with the patient's interdisciplinary team so that optimal outcomes of care may be achieved. It is imperative that the conditions of coverage specify the responsibilities of a qualified social worker so that dialysis clinics do not assign social workers inappropriate tasks and responsibilities. Tasks that are clerical in nature or involve admissions, transportation, travel, billing, and determining insurance coverage prohibit nephrology social workers from performing the clinical tasks central to their mission (Callahan, Witten & Johnstone, 1997). Russo (2002) found among the nephrology social workers that he surveyed 53% were responsible for making transportation arrangements for patients, and 46% of the nephrology social workers in his survey were responsible for making dialysis transient arrangements (which involved copying and sending patient records to out-of-town units). Only 20% of his respondents were able to do patient education. In the Promoting Excellence in End-of-Life Care 2002 report, End-Stage Renal Disease Workgroup Recommendations to the Field, it was recommend that dialysis units discontinue using master's level social workers for clerical tasks to ensure that they will have sufficient time to provide clinical services to their patients and their families. Merighi and Ehlebracht (2004b; 2004c; 2005), in a survey of 809 randomly sampled dialysis social workers in the United States, found that:

- 94% of social workers did clerical tasks, and that 87% of those respondents considered these tasks to be outside the scope of their social work training.
- 61% of social workers were solely responsible for arranging patient transportation.
- 57% of social workers were responsible for making travel arrangements for patients who were transient, which required 9% of their work time.

- 26% of social workers were responsible for initial insurance verification.
- 43% of social workers tracked Medicare coordination of benefit periods.
- 44% of social workers were primarily responsible for completing patient admission paperwork.
- 18% of social workers were involved in collecting fees from patients. (Respondents noted that this could significantly diminish trust and cause damage to the therapeutic relationship).
- Respondents spent 38% of their time on insurance, billing and clerical tasks vs. 25% of their time spent assessing and counseling patients.
- Only 34% of the social workers thought that they had enough time to sufficiently address patients' psychosocial needs.

This evidence clearly demonstrates that without clear definition and monitoring of responsibilities assigned to the qualified social work (as is the current case), social workers are routinely assigned tasks that are inappropriate, preventing them from doing appropriate tasks. For all of these reasons, CNSW is strongly urging the addition of "personnel responsibilities" to the new conditions of coverage (either in this section, or the next section).

Change the language of d to: *Social worker.* The facility must have a qualified social worker who—(1) Has completed a course of study with specialization in clinical practice, and holds a masters degree from a graduate school of social work accredited by the Council on Social Work Education; (2) Meets the licensing requirements for social work practice in the State in which he or she is practicing; and (3) Is responsible for the following tasks: initial and continuous patient assessment and care planning including the social, psychological, cultural and environmental barriers to coping to ESRD and prescribed treatment; provide emotional support, encouragement and supportive counseling to patients and their families or support system; provide individual and group counseling to facilitate adjustment to and coping with ESRD, comorbidities and treatment regimes, including diagnosing and treating mood disorders such as anxiety, depression, and hostility; providing patient and family education; helping to overcome psychosocial barriers to transplantation and home dialysis; crisis intervention; providing education and help completing advance directives; promoting self-determination; assisting patients with achieving their rehabilitation goals (including: overcoming barriers ; providing patients with education and encouragement regarding rehabilitation; providing case management with local or state vocational rehabilitation agencies); providing staff in-service education regarding ESRD psychosocial issues; recommending topics and otherwise participating in the facility's quality assurance program; mediating conflicts between patients, families and staff; participating in interdisciplinary care planning and collaboration, and advocating on behalf of patients in the clinic and community-at-large. The qualified social worker will not be responsible for clerical tasks related to transportation, transient arrangements, insurance or billing, but will supervise the case aide who is responsible for these tasks.

Rationale & References: Clinical social work training is essential to offer counseling to patients for complex psychosocial issues related to ESRD and its treatment regimes. Changing the language of this definition will make the definition congruent to that of a qualified social worker that is recommended by CNSW for the transplant conditions of coverage. CNSW supports the elimination of the "grandfather" clause of the previous conditions of coverage, which exempted individuals hired prior to the effective date of the existing regulations (September 1, 1976) from the social work master's degree requirement. As discussed in the preamble for these conditions, we recognize the importance of the professional social worker, and we believe there is a need for the requirement that the social worker have a master's degree. We agree that since the extension of Medicare coverage to individuals with ESRD, the ESRD patient population has become increasingly more complex from both medical and psychosocial perspectives. In order to meet the many and varied psychosocial needs of this patient population, we agree that qualified master's degree social workers (MSW) trained to function autonomously are essential. We agree that these social workers must have knowledge of individual behavior, family dynamics, and the psychosocial impact of chronic illness and treatment on the patient and family. This is why we argue that a specialization in clinical practice must be maintained in the definition.

Master's level social workers are trained to think critically, analyze problems, and intervene within areas of need that are essential for optimal patient functioning, and to help facilitate congruity between individuals and resources in the environment, demands and opportunities (Coulton, 1979; McKinley & Callahan, 1998; Morrow-Howell, 1992; Wallace, Goldberg, & Slaby, 1984). Social workers have an expertise of combining social context and utilizing community resource information along with knowledge of personality dynamics. The master of social work degree (MSW) requires two years of coursework and an additional 900 hours of supervised agency experience beyond what a baccalaureate of social work degree requires. An MSW curriculum is the only curriculum, which offers additional specialization in the biopsychosocialcultural, person-in-environment model of understanding human behavior. An undergraduate degree in social work or other mental health credentials (masters in counseling, sociology, psychology or doctorate in psychology, etc.) do not offer this specialized and comprehensive training in bio-psycho-social assessment and interaction between individual and the social system that is essential in dialysis programs. The National Association of Social Workers Standards of Classification considers the baccalaureate degree as a basic level of practice (Bonner & Greenspan, 1989; National Association of Social Workers, 1981). Under these same standards, the Masters of Social Work degree is considered a specialized level of professional practice and requires a demonstration of skill or competency in performance (Anderson, 1986). masters-prepared social workers are trained in conducting empirical evaluations of their own practice interventions (Council on Social Work Education). Empirically, the training of a masters-prepared social worker appears to be the best predictor of overall performance, particularly in the areas of psychological counseling, casework and case management (Booz & Hamilton, Inc., 1987; Dhooper, Royse & Wolfe, 1990). The additional 900 hours of supervised

and specialized clinical training in an agency prepares the MSW to work autonomously in the dialysis setting, where supervision and peer support is not readily available. This additional training in the biopsychosocial model of understanding human behavior also enables the masters-prepared social worker to provide cost-effective interventions such as assessment, education, individual, family and group therapy and to independently monitor the outcomes of these interventions to ensure their effectiveness.

The chronicity of end stage renal disease and the intrusiveness of required treatment provide renal patients with multiple psychosocial stressors including: cognitive losses, social isolation, bereavement, coping with chronic illness, concern about worsening health and death, depression, anxiety, hostility, psycho-organic disorders, somatic symptoms, lifestyle, economic pressures, insurance and prescription issues, employment and rehabilitation barriers, mood changes, body image issues, concerns about pain, numerous losses (income, financial security, health, libido, strength, independence, mobility, schedule flexibility, sleep, appetite, freedom with diet and fluid), social role disturbance (familial, social, vocational), dependency issues, and diminished quality of life (DeOreo, 1997; Gudes, 1995; Katon & Schulberg, 1997; Kimmel et al., 2000; Levenson, 1991; Rabin, 1983; Rosen, 1999; Vourlekis & Rivera-Mizzoni, 1997). The gravity of these psychosocial factors necessitates an assessment and interventions conducted by a qualified social worker as outlined above.

It is clear that social work intervention can maximize patient outcomes:

- Through patient education and other interventions, nephrology social workers are successful in improving patient's adherence to the ESRD treatment regime. Auslander and Buchs (2002), and Root (2005) have shown that social work counseling and education led to reduced fluid weight gains in patients. Johnstone and Halshaw (2003) found in their experimental study that social work education and encouragement were associated with a 47% improvement in fluid restriction adherence.
- Beder and colleagues (2003) conducted an experimental research study to determine the effect of cognitive behavioral social work services. They found that patient education and counseling by nephrology social workers was significantly associated with increased medication compliance. This study also determined that such interventions improved patients' blood pressure. Sikon (2000) discovered that social work counseling can reduce patients' anxiety level. Several researchers have determined that nephrology social work counseling significantly improves ESRD patient quality of life (Chang, Winsett, Gaber & Hathaway, 2004; Frank, Auslander & Weissgarten, 2003; Johnstone, 2003).

Nephrology social work interventions also tend to be valued by patients. Siegal, Witten, and Lundin's 1994 survey of ESRD patients found that 90% of respondents "believed that access to a nephrology social worker was important" (p.33) and that patients relied on nephrology social workers to assist them with coping, adjustment, and rehabilitation. Dialysis patients have ranked a "helpful social worker" as being more important to them than nephrologists or nurses (Rubin, et al., 1997). In a study by Holley, Barrington, Kohn and Hayes (1991), 70% of patients said that social workers gave the most useful information about

treatment modalities compared to nurses and physicians. These researchers also found that patients thought that social workers were twice as helpful as nephrologists in helping them to choose between hemodialysis and peritoneal dialysis for treatment.

GWEN REISNER
3 Lucerne Court
Cherry Hill, NJ 08003

May 1, 2005

Centers for Medicare and Medicaid Services
Attention: CMS - 3818 - P
P.O. Box 8012
Baltimore, Md 21244-8012

COMMENTS: CMS - 3818 - P
42 CFR Parts 400, 410, 412, 413, 414, 488 and 494
Medicare Program: Conditions for Coverage for End Stage Renal Disease Facilities

To Whom It May Concern:

Attached are my comments for the Medicare Program's Conditions for Coverage for End Stage Renal Disease Facilities. I have reviewed the comments by the Council of Nephrology Social Workers and agree with them fully. Therefore, I am submitting there comments as a representation of my own.

Sincerely,

Gwen Reisner MSW
LCSW

Gwen Reisner
3 Lucerne Court
Cherry Hill, NJ 08003

Issue Identifier	CNSW Comment on Conditions for Coverage for End Stage Renal Disease Facilities File code CMS–3818–P pg 1
LOCATION OF COC	PROPOSED DIALYSIS COC that are identified in this document can be found at: http://a257.g.akamaitech.net/7/257/2422/09feb20050800/edocket.access.gpo.gov/2005/pdf/05-1622.pdf
494.10 Definitions Dialysis facility *NEW* Staff assisted skilled nursing home dialysis	***Add:*** A new category for dialysis provided in a nursing home setting ***Rationale***: Nursing home dialysis is typically provided by staff. Home dialysis (PD or home hemodialysis) is typically performed by a trained *patient* and/or a helper. Making these treatments equivalent ignores the important differences between them, including the staff training/supervisory needs of nursing home dialysis patients. ***Reference:*** Tong & Nissenson, 2002
494.20. Condition Compliance with Federal, State, and local laws and regulations	***Add:*** "Facilities must accommodate mobility, hearing, vision, or other disabilities or language and communication barriers" ***Rationale***: Healthcare settings are covered entities under the Americans with Disabilities Act. ***References:*** ADA
494.60 Condition Physical Environment. (c) Patient care environment	***Add to c1***: Require facilities to be accessible to people with disabilities. ***Rationale***: Americans with Disabilities Act ***Reference:*** ADA ***Add to c1***: Require facilities to have a place for confidential interviews with patients and families and to provide for privacy during body exposure. ***Rationale***: HIPAA privacy ***Reference:*** *Protecting the Privacy of Patients' Health Information* ***Comment***: CNSW Supports the inclusion of the proposed (c) (2) regarding facility temperature. ***Rationale***: A common complaint from dialysis patients is in regards to the facility climate. A patient-centered care approach dictates that facilities need to have a plan in place to accommodate patients' preferences for climate, and address the concerns of patients who are not comfortable.
494.70 Condition Patients' Rights (a) Standard: Patients' rights	***Add***: (2) Require facility to ask the patient to *demonstrate understanding* of information provided. ***Rationale***: Without this requirement, it would be very easy for staff to believe that they had informed a patient without realizing that, in fact, the patient did not understand the information. ***References:*** Johnstone, 2004; Juhnke & Curtin, 2000; Kaveh & Kimmel, 2001 ***Comment & Addition to a6:*** CNSW supports the language of a6 with the recommended addition of requiring facilities to inform patients of all available treatments (in-center hemodialysis, CAPD, CCPD, conventional home hemodialysis, daily home hemodialysis, nocturnal home hemodialysis, transplant), and to provide a list of facilities where treatments are offered within 120 miles if the facility does not offer that treatment. ***Rationale:*** We propose to require that a facility inform patients about all available treatment modalities

and settings, so patients can make an informed decision regarding the most appropriate course of treatment that meets their needs. To assist dialysis patients in achieving the optimal quality of life, patients need education about each modality and must have access to the widest array of treatment choices possible. For patients to truly have choices in their modalities, they must not only know what types of treatment exist, but where they can be obtained. Home Dialysis Central (www.homedialysis.org) has a searchable database of clinics that offer any type of home dialysis and US maps for each home modality showing a 120 mile radius from clinic locations.

Comment: CNSW supports the language of a5
Rationale: Advance directives establish in writing an individual's preference with respect to the degree of medical care and treatment desired or who should make treatment decisions if the individual should become incapacitated and lose the ability to make or communicate medical decisions.

Add: (new 17) "Have access to a qualified social worker and dietitian as needed"
Rationale: Social workers and dietitians often have large caseloads, cover multiple clinics and/or work part-time, and patients often do not know how to contact them when needed.
References: Bogatz, Colasanto, Sweeney, 2005; Forum of ESRD Networks, 2003; Merighi & Ehlebracht, 2004a

Add: (new 18) "Be informed that full- or part-time employment and/or schooling is possible on dialysis"
Rationale: New patients do not know what to expect from dialysis and may be told that they must go on disability, when paid employment (with insurance) or schooling may be possible for them, particularly if they have access to evening shifts, transplant or home dialysis therapies. The purpose of dialysis is to permit the highest possible level of functioning despite kidney failure, thus this element of rehabilitation is crucial.
References: Curtin et al,1996; Rasgon et al, 1993, 1996

Add: (new 19) "Have a work-friendly modality (PD or home hemodialysis) or schedule that accommodates work or school"
Rationale: Same as above for new 18.
References: Same as above for new 18, plus:Mayo 1999

Add: (new 20) "Receive referral for physical or occupational therapy, and/or vocational rehabilitation as needed"
Rationale: These interventions have been shown to improve patient rehabilitation outcomes.
References: Beder, 1999; Dobrof et al., 2001; Witten, Howell & Latos, 1999.

Add: (new 21) "Attend care planning meetings with or without representation."
Rationale: Promoting patient participation in care requires that patients have the right to attend their own care planning meetings.

Add: (new 22) "Request an interdisciplinary conference with the care team, medical director and/or nephrologists."
Rationale: Patients don't realize that they can convene a care conference, and this is one way to obtain feedback from the team outside of the normal care planning meeting, which might only be done once/year.

Add: (new 23) "Refuse cannulation by a nurse or technician if access problems occurred with that staff member in the past until evidence of retraining is provided. Patients may also request another staff person to observe cannulation."
Rationale: Patients have only a limited number of potential vascular access sites, and if a staff person was responsible for causing access damage or hospitalization in the past, patients must have the right to protect themselves by refusing care from that staff person. Despite the obvious interpersonal and convenience issues this will cause for facilities, this is a patient safety issue that also has the potential to reduce cost to the system of hospitalization from vascular access problems. This will also encourage clinics to help their staff improve their cannulation skills and teach patients to self-cannulate.

Add: (new 24) "Be informed that self-cannulation is possible and be offered training to self cannulate."
Rationale: Having a single, consistent cannulator can help preserve vascular accesses and reduce hospitalizations. Since the patient is always present for the hemodialysis treatment, he or she should be encouraged whenever possible to become his/her own cannulator. Clinics should not be allowed to have a policy denying a willing patient the right to learn to self-cannulate.

Add: (new 25) "Be informed of topical analgesics for needle pain and how to obtain them"
Rationale: Needle fear and needle pain are largely unaddressed issues in hemodialysis, despite the large (14-15 gauge) needles that must be used at each treatment. Patients should be able to undergo a painless treatment, and low-cost, over-the-counter, 4% lidocaine preparations are available that will not harm the access and will provide pain relief. Patients should be told that these products exist and where to obtain them.
Reference: McLaughlin et al., 2003

Add: (new 26) "Receive counseling from a qualified social worker to address concerns related to the patient's adjustment to illness, including changes to life-style and relationships because of his illness, developmental issues affected by his illness, and any behavior that negatively affects his health or standing in the facility."

	Rationale: Patients are faced with numerous adjustment issues due to ESRD and its treatment regimes. Master's level social workers are trained to intervene within areas of need that are essential for optimal patient functioning and adjustment ***References:*** McKinley & Callahan, 1998; Vourlekis & Rivera-Mizzoni, 1997
494.70 Condition Patients' Rights (b) Standard: Right to be informed regarding the facility's discharge and transfer policies.	***Add to b1***: "Receive counseling and support from the team to resolve behavioral issues and be informed of behaviors that will lead staff to notify police or refer for evaluation of risk to self or others" ***Rationale***: Facilities should be encouraged first to try counseling to resolve difficult situations ***References:*** Forum of ESRD Networks, 2003; Johnstone S, et al, 1997; King & Moss, 2004; Rau-Foster, 2001; Renal Physicians Association and American Society of Nephrology, 2000 ***Add***: (new 2) "Not be involuntarily discharged from the facility for non-adherence with the treatment plan, including missing or shortening in-center hemodialysis treatments, excessive fluid weight gain, or lab tests that would suggest dietary indiscretions unless it can be shown that the patient's behavior is putting other patients or the facility operations at risk." ***Rationale:*** The ESRD Networks and the preamble of these proposed Conditions for Coverage have both stated that non-compliance should not be a basis for involuntary discharge from lifesaving dialysis treatment. Patients often are not educated as to the reasons why these behaviors may be harmful to them; it is therefore inappropriate to refuse them care due to their lack of knowledge. If consistent difficulties are noted with a patients' ability to follow the treatment plan, a team evaluation should be initiated to investigate and address all potential factors. For example, a patient who is trying to maintain a full-time job to support a family may choose to leave treatment early rather than risk losing employment; or a patient who is taking a medication that causes dry mouth may be unable to follow the fluid limits for in-center hemodialysis. ***References:*** Forum of ESRD Networks, 2003; Johnstone S, et al., 1997; King & Moss, 2004; Rau-Foster, 2001; Renal Physicians Association and American Society of Nephrology, 2000 ***Change***: (renumbered 3) Delete or define "reducing...ongoing care." ***Rationale:*** This phrase is unclear.
494.70 Condition Patients' Rights (c) Standard: Posting of rights.	***Add***: "Facilities with patients who cannot read the patients' rights poster must provide an alternate method to inform these patients of their rights which can be verified at survey." ***Rationale & References***: Americans with Disabilities Act, Civil Rights Act
494.80 Condition Patient assessment (a) Standard: Assessment criteria.	***Change***: The language of "social worker" in the first sentence to "qualified social worker" ***Rationale***: This will clarify any ambiguity of the social work role. ***Add***: (a1) "...and functioning and well-being using the SF-36 or other standardized survey that permits reporting of or conversion to a physical component summary (PCS) score and mental component

summary (MCS) score and all domains of functioning and well-being measured by that survey. If the MCS or mental health domain score is low, assess for major depression using the PHQ-2 or another validated depression survey or referring the patient to further mental health evaluation."
Rationale: The preamble to the *Conditions for Coverage* discussed the importance of measuring functioning and well-being—but stated that there was "no consensus" about which measure to use. In fact, the literature clearly supports the value of the PCS and MCS scores to independently predict morbidity and mortality among tens of thousands of ESRD patients—and these scores can be obtained from any of the tools currently in use to measure functioning and well-being. The composite scores (PCS and MCS) have been proven to be as predictive of hospitalization and death as serum albumin or Kt/V. Scores can be improved through qualified social work interventions.
References; DeOreo, 1997; Kalantar-Zadeh, Kopple, Block, Humphreys, 2001; Knight et al. 2003; Kroenke, Spitzer & Williams, 2003; Lowrie, Curtin, LePain & Schatell, 2003; Mapes et al., 2004

Comment: CNSW supports the language of a2, a3, a4, a5, a6

Change: (a7) to "Evaluation of psychosocial needs (such as but not limited to: coping with chronic illness, anxiety, mood changes, depression, social isolation, bereavement, concern about mortality & morbidity, psycho-organic disorders, cognitive losses, somatic symptoms, pain, anxiety about pain, decreased physical strength, body image issues, drastic lifestyle changes and numerous losses of [income, financial security, health, libido, independence, mobility, schedule flexibility, sleep, appetite, freedom with diet and fluid], social role disturbance [familial, social, vocational], dependency issues, diminished quality of life, relationship changes; psychosocial barriers to optimal nutritional status, mineral metabolism status, dialysis access, transplantation referral, participation in self care, activity level, rehabilitation status, economic pressures, insurance and prescription issues, employment and rehabilitation barriers)."
Rationale: Much like the elaboration of a1, a4, a8, a9, elaborating what "psychosocial issues" entails will ensure national coherence of the exact psychosocial issues that must be assessed for each patient. There is clear literature that identifies these psychosocial issues throughout this response.

Comment: CNSW supports the language of a8

Add: (a9)(new i) "The facility must include in its evaluation a report of self-care activities the patient performs. If the patient does not participate in care, the basis for nonparticipation must be documented in the medical record (i.e., cognitive impairment, refusal, etc.)."
Rationale: Life Options research has found that patients on dialysis 15 years or longer who participated actively in their own care did better; follow-up research with a random sample of 372 in-center hemodialysis patients found participation in self-care is correlated with higher functioning and well-being, which, in turn, predicts reduced hospitalization and mortality.

	References: Curtin, Bultman, Schatell & Chewning, 2004; Curtin & Mapes, 2001 ***Add***: (9)(new ii) "If the patient is not referred for home dialysis, the basis for non-referral must be documented in the medical record. Lack of availability of home dialysis in the facility is not a legitimate basis for non-referral." ***Rationale:*** Requiring that the basis for non-referral for home dialysis be documented will help to ensure that patients have access to these therapies and will provide needed data for QAPI purposes. ***Comment:*** CNSW supports the language of a10, a11, a12, a13
494.80 Condition Patient assessment (b) Standard. Frequency of assessment for new patients	***Change***: (b1) to "An initial comprehensive assessment and patient care plan must be conducted within 30 calendar days after the first dialysis treatment." ***Rationale***: We recommend combining an initial team assessment and care plan as they work in concert: a care plan should address areas for intervention as identified in the assessment. Permitting 30 days for assessment and development of a care plan allows for full team participation and adequate assessment of patient needs. ***Comment:*** CNSW supports the language of b2
494.80 Condition Patient assessment (d) Standard: Patient reassessment	***Change***: (d2iii) to "significant change in psychosocial needs as identified in 494.80 a7." ***Rationale***: Referring back to the specific psychosocial issues recommended to be added to 494.80 a7 will eliminate any ambiguity of needs to reassess ***Add***: (v) "Physical debilitation per patient report, staff observation, or reduced physical component summary (PCS) score on a validated measure of functioning and well-being." ***Rationale:*** Low PCS scores predict higher morbidity and mortality in research among ESRD patients. ***References:*** DeOreo, 1997; Kalantar-Zadeh, Kopple, Block, Humphreys, 2001; Knight et al. 2003; Kroenke, Spitzer & Williams, 2003; Lowrie, Curtin, LePain & Schatell, 2003; Mapes et al., 2004 ***Add***: (new vi) "Diminished emotional well-being per patient report, staff observation, or reduced mental component summary (MCS) score on a validated measure of functioning and well-being." ***Rationale:*** Low MCS scores predict higher morbidity and mortality in research among ESRD patients. Low MCS scores are also linked to depression and skipping dialysis treatments. ***References:*** DeOreo, 1997; Kalantar-Zadeh, Kopple, Block, Humphreys, 2001; Knight et al. 2003; Kroenke, Spitzer & Williams, 2003; Lowrie, Curtin, LePain & Schatell, 2003; Mapes et al., 2004 ***Add***: (new vii) "Depression per patient report, staff observation or validated depression screening survey" ***Rationale:*** Multiple studies report a high prevalence of untreated depression in dialysis patients;

	depression is an independent predictor of death. ***References;*** Andreucci et al., 2004.; Kimmel, 1993; Kimmel, 1998; Kutner et al., 2000.; Wuerth, Finklestein & Finklestein, 2005 ***Add***: (new viii) "Loss of or threatened loss of employment per patient report" ***Rationale***: Poor physical and mental health functioning have been linked to increased hospitalizations and death. Loss of employment is linked to depression, social isolation, financial difficulties, and loss of employer group health plan coverage. Identifying low functioning patients early and targeting interventions to improve their functioning should improve their physical and mental functioning and employment outcomes. ***References;*** Blake, Codd, Cassidy & O'Meara, 2000; Lowrie, Curtin, LePain & Schatell, 2003; Mapes et al., 2004; Witten, Schatell & Becker, 2004
494.90 Condition Patient plan of care. (a) Standard: Development of patient plan of care.	***Add***: (a) the *patient* to those developing the plan and include: "If the patient or his or her representative does not participate in care planning, the basis for nonparticipation must be noted in the patient's medical record, the patient or his or her representative must initial the reason provided, and sign the care plan." ***Rationale***: The patient must be explicitly listed as part of the care planning process ***Add***: (new 3) "*Psychosocial status*. The interdisciplinary team must provide the necessary care and services to achieve and sustain an effective psychosocial status." ***Rationale & References***: Eighty-nine percent of ESRD patients report experiencing significant lifestyle changes from the disease (Kaitelidou, et al., 2005). The chronicity of end stage renal disease and the intrusiveness of its required treatment provide renal patients with multiple disease-related and treatment-related psychosocial stressors that affect their everyday lives (Devins et al., 1990). Researchers including Auslander, Dobrof & Epstein (2001), Burrows-Hudson (1995), and Kimmel et al. (1998) have found that psychosocial issues negatively impact health outcomes of patients and diminish patient quality of life. Therefore, "psychosocial status" must be considered as equally important as other aspects of the care plan. ***Add***: (new 6) Home dialysis status. All patients must be informed of *all* home dialysis options, including CAPD, CCPD, conventional home hemodialysis, daily home hemodialysis, and nocturnal home hemodialysis, and be evaluated as a home dialysis candidate. When the patient is a home dialysis candidate, the interdisciplinary team must develop plans for pursuing home dialysis. The patient's plan of care must include documentation of the (i) Plan for home dialysis, if the patient accepts referral for home dialysis; (ii) Patient's decision, if the patient is a home dialysis candidate but declines home dialysis; or (iii) Reason(s) for the patient's non-referral as a home dialysis candidate as documented in accordance

	with § 494.80(a)(9)(ii) of this part. ***Rationale***: Home therapies allow greater flexibility, patient control, fewer dietary and fluid restrictions, need for fewer medications, potential for improved dialysis adequacy, and improved likelihood of employment. CMS has stated encouragement of home dialysis as a goal. Every patient must be informed of home dialysis options, evaluated for candidacy for home dialysis, and, if not a candidate, the reason(s) why not should be reported. This allows quality assessment and improvement activities to be undertaken in the area of home dialysis. ***Add***: (renumbered 8) "Rehabilitation status. The interdisciplinary team must provide the necessary care and services to: (i) maximize physical and mental functioning as measured minimally by physical component summary (PCS) score and mental component summary (MCS) score on a validated measure of functioning and well-being (or an equally valid indicator of physical and mental functioning), (ii) help patients maintain or improve their vocational status (including paid or volunteer work) as measured by annually tracking the same employment categories on the CMS 2728 form (iii) help pediatric patients (under the age of 18 years) to obtain at least a high school diploma or equivalency as measured by annually tracking student status. (iv) Reasons for decline in rehabilitation status must be documented in the patient's medical record and interventions designed to reverse the decline." ***Rationale***: The goals of the current proposed section are vague, not measurable, and not actionable. To improve rehabilitation outcomes, facilities must meet certain standards. From the perspective of the Medical Education Institute, which administers the Life Options Rehabilitation Program, "rehabilitation" can be measured by a functioning and well-being vocational assessment. Functioning and well-being (measured minimally as PCS and MCS) predict morbidity and mortality. Annually tracking employment status through Networks using the same categories on the CMS 2728 and including this as a QAPI would improve the likelihood that rehabilitation efforts would be successful.
494.90 Condition Patient plan of care. (b) Standard: Implementation of the patient care plan.	***Add to 3b***: "If the expected outcome is not achieved, the interdisciplinary team must describe barriers encountered, adjust the patient's plan of care to either achieve the specified goals or establish new goals, and explain why new goals are needed." ***Rationale***: When goals are not met, barriers must be identified and goals re-examined for feasibility of success. Sometimes barriers can be eliminated so original goals can be met; other times, new goals must be set that are more reasonable.
494.90 Condition Patient plan of care. (c) Standard: Transplantation referral tracking	***Comment:*** CNSW supports the language of (c) and recommends its inclusion in the final conditions. In addition, we would also like to see language which would outline the responsibilities of transplant centers and their responsibilities for following up and informing dialysis units of the transplant status of patients referred for transplant.

494.90 Condition Patient plan of care. (d) Standard: Patient education and training.	***Add to d***: "The patient care plan must include, as applicable, education and training for patients and family members or caregivers or both, and must document training the following areas in the patient's medical record: (i) The nature and management of ESRD (ii) The full range of techniques associated with treatment modality selected, including effective use of dialysis supplies and equipment in achieving and delivering the physician's prescription of Kt/V or URR, and effective erythropoietin administration (if prescribed) to achieve and maintain a hemoglobin level of at least 11 gm/dL (iii) How to follow the renal diet, fluid restrictions, and medication regimen (iv) How to read, understand, and use lab tests to track clinical status (v) How to be an active partner in care (vi) How to achieve and maintain physical, vocational, emotional and social well-being (vii) How to detect, report, and manage symptoms and potential dialysis complications (viii) What resources are available in the facility and community and how to find and use them (ix) How to self-monitor health status and record and report health status information (x) How to handle medical and non-medical emergencies (xi) How to reduce the likelihood of infections (x) How to properly dispose of medical waste in the dialysis facility and at home **Rationale**: Life Options Research has demonstrated among 372 randomly-selected in-center hemodialysis patients that higher levels of dialysis knowledge are correlated with higher mental component summary (MCS) scores on the SF-12, which are, in turn, predictive of longer survival and lower hospitalization. The specific aspects of education delineated above are what Life Options believes to be core skills that ESRD patients must gain in order to become active partners in care, producing their own best health outcomes and monitoring the safety and quality of the care that is delivered to them. ***References;*** Curtin, et al. 2002; Curtin, Klag, Bultman & Schatell, 2002; Curtin, Sitter, Schatell & Chewning, 2004; Johnstone, et al., 2004
494.100 Condition Care at home.	***Comment:*** CNSW agrees that services to home patients should be at least equivalent to those provided to in-center patients. **Rationale**: Home dialysis patients are patients of the ESRD facility and are entitled to the same rights, services, and efforts to achieve expected outcomes as any other patient of the facility. ***Add***: (new 3iv) "Implementation of a social work care plan" ***Rationale & References***: Eighty-nine percent of ESRD patients report experiencing significant lifestyle changes from the disease (Kaitelidou, et al., 2005). The chronicity of end stage renal disease and the intrusiveness of treatment provide renal patients with multiple disease-related and treatment-related psychosocial stressors that affect their everyday lives (Devins et al., 1990). Researchers including Auslander, Dobrof & Epstein (2001), Burrows-Hudson (1995), and Kimmel et al. (1998) have found that

	psychosocial issues negatively impact health outcomes of patients and diminish patient quality of life. Therefore, a social work care plan is as equally important as other aspects of training for home patients. It is important to specify a "social work care plan" to ensure that it is conducted by a qualified social worker as identified below.
494.100 Condition Care at home. (c) Standard: Support services.	***Add to 1i***: "Periodic monitoring of the patient's home adaptation, including at minimum an annual visit to the patient's home by all facility personnel if geographically feasible (RN, social worker, dietitian, and machine technician) in accordance with the patient's plan of care." ***Rationale***: Members of the interdisciplinary team can offer better care to patients after seeing the patient in his/her home environment where they can observe barriers and supports first-hand. The members should be specified to ensure equal visitation of the team members across all dialysis units. The language of this part of the proposed conditions is vague and subject to varying interpretation (i.e. exactly who are the "facility personnel" who will visit the patient's home?) ***Add to 1iv***: "Patient consultation with all members of the interdisciplinary team, as needed." ***Rationale***: The language of this part of the proposed conditions is vague and subject to varying interpretation
NEWCONDITION Staff assisted skilled nursing home dialysis	***Add:*** A new condition for dialysis provided in a nursing home setting (that is not incorporated into the "home" condition 494.100) ***Rationale***: Nursing home dialysis is typically provided by staff. Home dialysis (PD or home hemodialysis) is typically performed by a trained patient and/or a helper. Making these treatments equivalent obscures important differences between them, including the staff training/supervisory needs of nursing home dialysis patients. To include care in a nursing facility/skilled nursing facility (NF/SNF) under "care at home" is inappropriate. There is a tremendous difference in what CMS must do to protect the health and safety of highly functioning, trained patients who do self-care at home (or have assistance from a trained helper at home) and patients who require personnel in an NF/SNF to perform dialysis because they are too debilitated to travel to a dialysis facility. ***Reference:***Tong & Nissenson, 2002 ***Add:*** Language to this proposed condition that would mandate " A Nursing facility/Skilled Nursing Facility providing full-care dialysis to residents with ESRD, must be certified as a dialysis facility and comply with all sections of this rule, including personnel qualifications." ***Rationale***: Patients receiving dialysis in NF or SNF should not be deprived of essential services that they would normally receive in an outpatient dialysis facility, including consultation with a qualified nephrology social worker. While NFs and SNFs may employ social workers, these social workers may not hold a master's degree and will not have the specialized knowledge of the complex social and emotional factors affecting the dialysis patient. To ensure that the health and safety of NF or SNF hemodialysis patients is protected, any proposed requirements should specifically incorporate Secs 494.70, 494.80 and 494.90 of

	the proposed conditions of coverage.
§494.110 Condition Quality assessment and performance improvement. (a) Standard: Program scope.	***Add***: (1) "The program must include, but not be limited to, an ongoing program that achieves measurable improvement in physical, mental, and clinical health outcomes and reduction of medical errors by using indicators or performance measures associated with improved physical and mental health outcomes and with the identification and reduction of medical errors." ***Rationale:*** To ensure patient-centered care, patient functioning and well-being must be one of the quality indicators that is monitored and improved. ***Add***: (2)(new iii) "Psychosocial status." ***Rationale & References***: Eighty-nine percent of ESRD patients report experiencing significant lifestyle changes from the disease (Kaitelidou, et al., 2005). The chronicity of end stage renal disease and the intrusiveness of its required treatment provide renal patients with multiple disease-related and treatment-related psychosocial stressors that affect their everyday lives (Devins et al., 1990). Researchers including Auslander, Dobrof & Epstein (2001), Burrows-Hudson (1995), and Kimmel et al. (1998) have found that psychosocial issues negatively impact health outcomes of patients and diminish patient quality of life. Therefore, "psychosocial status" must be considered as equally important as other aspects of quality improvement. CNSW has many resources and tools, available through the National Kidney Foundation, that can be used to track social work quality. ***Add***: (2)(new ix) "Functioning and well-being as measured by physical component summary (PCS) and mental component summary (MCS) scores (or other equally valid measure of mental and physical functioning) and vocational status using the same categories as reported on the CMS 2728 form" ***Rationale:*** These scores provide a baseline and ongoing basis for QAPI activities to improve patient rehabilitation outcomes. ***Comment:*** CNSW agrees that dialysis providers must measure patient satisfaction and grievances. CNSW supports the use of a standardized survey (such as the one being currently developed by CMS) for measuring patients' experience and ratings of their care. Such a survey would provide information for consumer choice, reports that facilities can use for internal quality improvement and external benchmarking against other facilities, and finally, information that can be used for public reporting and monitoring purposes. The survey should be in the public domain and consist of a core set of questions that could be used in conjunction with existing surveys.
494.140 Condition Personnel qualifications	***Comment:*** CNSW recommends that this section be renamed "Personnel qualifications and responsibilities", with the addition of specified personnel responsibilities to each team member's qualifications. If it is decided that adding "personnel responsibilities" to this section is inappropriate, we would suggest the alteration of 494.150 to be renamed "Condition: Personnel Responsibilities" and include a discussion of the responsibilities of each team member (instead of just the medical director as is

currently proposed). CNSW suggests possible responsibilities for social workers in the next section, where we comment on "494.140 Condition Personnel qualifications (d) Standard: Social worker." These suggestions can be used in a new "responsibilities" section.

Rationale & References: It is critically important to clearly delineate personnel responsibilities in some fashion in these new conditions of coverage to ensure that there is parity in the provision of services to beneficiaries in every dialysis unit in the country. It is just as important to outline each team member's responsibilities as it is the medical director's, as is currently proposed. This is especially important regarding qualified social work responsibilities. Currently, many master's level social workers are given responsibilities and tasks that are clerical in nature and which prevent the MSW from participating fully with the patient's interdisciplinary team so that optimal outcomes of care may be achieved. It is imperative that the conditions of coverage specify the responsibilities of a qualified social worker so that dialysis clinics do not assign social workers inappropriate tasks and responsibilities. Tasks that are clerical in nature or involve admissions, transportation, travel, billing, and determining insurance coverage prohibit nephrology social workers from performing the clinical tasks central to their mission (Callahan, Witten & Johnstone, 1997). Russo (2002) found among the nephrology social workers that he surveyed 53% were responsible for making transportation arrangements for patients, and 46% of the nephrology social workers in his survey were responsible for making dialysis transient arrangements (which involved copying and sending patient records to out-of-town units). Only 20% of his respondents were able to do patient education. In the Promoting Excellence in End-of-Life Care 2002 report, End-Stage Renal Disease Workgroup Recommendations to the Field, it was recommend that dialysis units discontinue using master's level social workers for clerical tasks to ensure that they will have sufficient time to provide clinical services to their patients and their families. Merighi and Ehlebracht (2004b; 2004c; 2005), in a survey of 809 randomly sampled dialysis social workers in the United States, found that:

- 94% of social workers did clerical tasks, and that 87% of those respondents considered these tasks to be outside the scope of their social work training.
- 61% of social workers were solely responsible for arranging patient transportation.
- 57% of social workers were responsible for making travel arrangements for patients who were transient, which required 9% of their work time.
- 26% of social workers were responsible for initial insurance verification.
- 43% of social workers tracked Medicare coordination of benefit periods.
- 44% of social workers were primarily responsible for completing patient admission paperwork.
- 18% of social workers were involved in collecting fees from patients. (Respondents noted that this could significantly diminish trust and cause damage to the therapeutic relationship).
- Respondents spent 38% of their time on insurance, billing and clerical tasks vs. 25% of their

	time spent assessing and counseling patients. • Only 34% of the social workers thought that they had enough time to sufficiently address patients' psychosocial needs. This evidence clearly demonstrates that without clear definition and monitoring of responsibilities assigned to the qualified social work (as is the current case), social workers are routinely assigned tasks that are inappropriate, preventing them from doing appropriate tasks. For all of these reasons, CNSW is strongly urging the addition of "personnel responsibilities" to the new conditions of coverage (either in this section, or the next section).
494.140 Condition Personnel qualifications (d) Standard: Social worker.	***Change the language of d to***: *Social worker.* The facility must have a qualified social worker who—(1) Has completed a course of study with specialization in clinical practice, and holds a masters degree from a graduate school of social work accredited by the Council on Social Work Education; (2) Meets the licensing requirements for social work practice in the State in which he or she is practicing; and (3) Is responsible for the following tasks: initial and continuous patient assessment and care planning including the social, psychological, cultural and environmental barriers to coping to ESRD and prescribed treatment; provide emotional support, encouragement and supportive counseling to patients and their families or support system; provide individual and group counseling to facilitate adjustment to and coping with ESRD, comorbidities and treatment regimes, including diagnosing and treating mood disorders such as anxiety, depression, and hostility; providing patient and family education; helping to overcome psychosocial barriers to transplantation and home dialysis; crisis intervention; providing education and help completing advance directives; promoting self-determination; assisting patients with achieving their rehabilitation goals (including: overcoming barriers ; providing patients with education and encouragement regarding rehabilitation; providing case management with local or state vocational rehabilitation agencies); providing staff in-service education regarding ESRD psychosocial issues; recommending topics and otherwise participating in the facility's quality assurance program; mediating conflicts between patients, families and staff; participating in interdisciplinary care planning and collaboration, and advocating on behalf of patients in the clinic and community-at-large. The qualified social worker will not be responsible for clerical tasks related to transportation, transient arrangements, insurance or billing, but will supervise the case aide who is responsible for these tasks. ***Rationale & References***: Clinical social work training is essential to offer counseling to patients for complex psychosocial issues related to ESRD and its treatment regimes. Changing the language of this definition will make the definition congruent to that of a qualified social worker that is recommended by CNSW for the transplant conditions of coverage. CNSW supports the elimination of the "grandfather" clause of the previous conditions of coverage, which exempted individuals hired prior to the effective date of the existing regulations (September 1, 1976) from the social work master's degree requirement. As discussed in the preamble for these conditions, we recognize the importance of the professional social worker, and we believe there is a need for the requirement that the social worker have a master's degree.

We agree that since the extension of Medicare coverage to individuals with ESRD, the ESRD patient population has become increasingly more complex from both medical and psychosocial perspectives. In order to meet the many and varied psychosocial needs of this patient population, we agree that qualified master's degree social workers (MSW) trained to function autonomously are essential. We agree that these social workers must have knowledge of individual behavior, family dynamics, and the psychosocial impact of chronic illness and treatment on the patient and family. This is why we argue that a specialization in clinical practice must be maintained in the definition.

Master's level social workers are trained to think critically, analyze problems, and intervene within areas of need that are essential for optimal patient functioning, and to help facilitate congruity between individuals and resources in the environment, demands and opportunities (Coulton, 1979; McKinley & Callahan, 1998; Morrow-Howell, 1992; Wallace, Goldberg, & Slaby, 1984). Social workers have an expertise of combining social context and utilizing community resource information along with knowledge of personality dynamics. The master of social work degree (MSW) requires two years of coursework and an additional 900 hours of supervised agency experience beyond what a baccalaureate of social work degree requires. An MSW curriculum is the only curriculum, which offers additional specialization in the biopsychosocialcultural, person-in-environment model of understanding human behavior. An undergraduate degree in social work or other mental health credentials (masters in counseling, sociology, psychology or doctorate in psychology, etc.) do not offer this specialized and comprehensive training in bio-psycho-social assessment and interaction between individual and the social system that is essential in dialysis programs. The National Association of Social Workers Standards of Classification considers the baccalaureate degree as a basic level of practice (Bonner & Greenspan, 1989; National Association of Social Workers, 1981). Under these same standards, the Masters of Social Work degree is considered a specialized level of professional practice and requires a demonstration of skill or competency in performance (Anderson, 1986). masters-prepared social workers are trained in conducting empirical evaluations of their own practice interventions (Council on Social Work Education). Empirically, the training of a masters-prepared social worker appears to be the best predictor of overall performance, particularly in the areas of psychological counseling, casework and case management (Booz & Hamilton, Inc., 1987; Dhooper, Royse & Wolfe, 1990). The additional 900 hours of supervised and specialized clinical training in an agency prepares the MSW to work autonomously in the dialysis setting, where supervision and peer support is not readily available. This additional training in the biopsychosocial model of understanding human behavior also enables the masters-prepared social worker to provide cost-effective interventions such as assessment, education, individual, family and group therapy and to independently monitor the outcomes of these interventions to ensure their effectiveness.

The chronicity of end stage renal disease and the intrusiveness of required treatment provide renal patients with multiple psychosocial stressors including: cognitive losses, social isolation, bereavement, coping with chronic illness, concern about worsening health and death, depression, anxiety, hostility, psycho-organic disorders, somatic symptoms, lifestyle, economic pressures, insurance and prescription

	issues, employment and rehabilitation barriers, mood changes, body image issues, concerns about pain, numerous losses (income, financial security, health, libido, strength, independence, mobility, schedule flexibility, sleep, appetite, freedom with diet and fluid), social role disturbance (familial, social, vocational), dependency issues, and diminished quality of life (DeOreo, 1997; Gudes, 1995; Katon & Schulberg, 1997; Kimmel et al., 2000; Levenson, 1991; Rabin, 1983; Rosen, 1999; Vourlekis & Rivera-Mizzoni, 1997). The gravity of these psychosocial factors necessitates an assessment and interventions conducted by a qualified social worker as outlined above. It is clear that social work intervention can maximize patient outcomes: • Through patient education and other interventions, nephrology social workers are successful in improving patient's adherence to the ESRD treatment regime. Auslander and Buchs (2002), and Root (2005) have shown that social work counseling and education led to reduced fluid weight gains in patients. Johnstone and Halshaw (2003) found in their experimental study that social work education and encouragement were associated with a 47% improvement in fluid restriction adherence. • Beder and colleagues (2003) conducted an experimental research study to determine the effect of cognitive behavioral social work services. They found that patient education and counseling by nephrology social workers was significantly associated with increased medication compliance. This study also determined that such interventions improved patients' blood pressure. Sikon (2000) discovered that social work counseling can reduce patients' anxiety level. Several researchers have determined that nephrology social work counseling significantly improves ESRD patient quality of life (Chang, Winsett, Gaber & Hathaway, 2004; Frank, Auslander & Weissgarten, 2003; Johnstone, 2003). Nephrology social work interventions also tend to be valued by patients. Siegal, Witten, and Lundin's 1994 survey of ESRD patients found that 90% of respondents "believed that access to a nephrology social worker was important" (p.33) and that patients relied on nephrology social workers to assist them with coping, adjustment, and rehabilitation. Dialysis patients have ranked a "helpful social worker" as being more important to them than nephrologists or nurses (Rubin, et al., 1997). In a study by Holley, Barrington, Kohn and Hayes (1991), 70% of patients said that social workers gave the most useful information about treatment modalities compared to nurses and physicians. These researchers also found that patients thought that social workers were twice as helpful as nephrologists in helping them to choose between hemodialysis and peritoneal dialysis for treatment.
494.140 Condition Personnel qualifications	***Add***: (e) Standard: Case aide. Dialysis units that have more than 75 patients per full time social worker must employ a case aide who- As supervised by the unit social worker, performs clerical tasks involving admissions, transfers, billing, transportation arrangements, transient treatment paperwork and verifies insurance coverage. ***Rationale & References***: We agree with the preamble that dialysis patients need essential social services

including transportation, transient arrangements and billing/insurance issues. We also firmly agree with the preamble that these tasks should not be handled by the qualified social worker (unless the social worker has fewer than 75 patients per full time equivalent social worker), as caseloads higher than this prevent the MSW from participating fully with the interdisciplinary team so that optimal outcomes of care may be achieved. It is imperative that the conditions of coverage identify a new team member who can provide social service assistance-the preamble recommends that these clerical tasks should be done by someone other than the MSW, but does not specify who that person is-adding this section (e) will eliminate any ambiguity surrounding this issue, and ensure adherence to this recommendation across all settings. Tasks that are clerical in nature or involve admissions, billing, and determining insurance coverage prevent nephrology social workers from performing the clinical tasks central to their mission (Callahan, Witten & Johnstone, 1997). Russo (2002) found that all of the nephrology social workers that he surveyed felt that transportation was not an appropriate task for them, yet 53% of respondents were responsible for making transportation arrangements for patients. Russo found that 46% of the nephrology social workers in his survey were responsible for making dialysis transient arrangements (which involved copying and sending patient records to out-of-town units), yet only 20% were able to do patient education. In the Promoting Excellence in End-of-Life Care's 2002 report, End-Stage Renal Disease Workgroup Recommendations to the Field, workgroup members recommended that dialysis units discontinue using master's level social workers for clerical tasks to ensure that they will have sufficient time to provide clinical services to their patients and their families. Merighi and Ehlebracht (2004b; 2004c; 2005), in a survey of 809 randomly sampled dialysis social workers in the United States, found that:

- 94% of social workers did clerical tasks, and that 87% of those respondents considered these tasks to be outside the scope of their social work training.
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- 57% of social workers were responsible for making travel arrangements for patients who were transient, taking 9% of their time.
- 26% of social workers were responsible for initial insurance verification.
- 43% of social workers tracked Medicare coordination periods.
- 44% of social workers were primarily responsible for completing admission packets.
- 18% of social workers were involved in collecting fees from patients. Respondents noted that this could significantly diminish therapeutic relationships and decrease trust.
- Respondents spent 38% of their time on insurance, billing and clerical tasks vs. 25% of their time spent counseling and assessing patients.
- Only 34% of the social workers thought that they had enough time to sufficiently address patient psychosocial needs.

This evidence clearly demonstrates that there needs to be another team member who can handle these clerical social service needs. This position would be cost-effective, as the person in this role can help

	patients obtain insurance coverage for dialysis that they normally would not have and increase facility's reimbursement. As discussed and referenced below in detail, CNSW recommends a ratio of 75 patients per full-time equivalent social worker. If a dialysis clinic has fewer patients per full-time equivalent social worker than less than 75:1, the social worker can address concrete social service needs of patients. However, patient ratios over 75 patients per full-time equivalent social worker require a case aide.
§494.180 **Condition** Governance. (b1) Standard. Adequate number of qualified and trained staff.	***Add***: (1i) No dialysis clinic should have more than 75 patients per one full time social worker. ***Rationale & References***: A specific social worker-patient ratio must be included in the conditions of coverage. Currently, there are no such national ratios and as a result social workers have caseloads as high as more than 300 patients per social worker in multiple, geographically separated, clinics. This is highly variable among different dialysis units-letting dialysis clinics establish their own ratios will leave ESRD care in the same situation as we have now with very high social work caseloads. For many years, CNSW has had an acuity-based social work-patient ratio (contact the National Kidney Foundation for the formula) which has been widely distributed to all dialysis units. This has largely been ignored by dialysis providers, who routinely have patient-to-social work ratios of 125-300. The new conditions of coverage must either identify an acuity-based social work staffing ratio model to be used in all units (we would recommend CNSW's staffing ratio), or set a national patient-social worker ratio. Leaving units to their own devices regarding ratios will not affect any change, as is evidenced by today's large caseloads and variability in such. CNSW has determined that 75:1 is the ideal ratio. If CMS refuses to include language about social work ratios, we strongly urge that the final conditions include language for "an acuity-based social work staffing plan developed by the dialysis clinic social worker" (rather than having nursing personnel who have limited understanding of social work training or role to determine social work staffing). Large nephrology social work caseloads have been linked to decreased patient satisfaction and poor patient rehabilitation outcomes (Callahan, Moncrief, Wittman & Maceda, 1998). It is also the case that social workers report that high caseloads prevent them from providing adequate clinical services in dialysis, most notably counseling (Merighi, & Ehlebracht, 2002, 2005). In Merighi and Ehlebracht's (2004a) survey of 809 randomly sampled dialysis social workers in the United States, they found that only 13% of full time dialysis social workers had caseloads of 75 or fewer, 40% had caseloads of 76-100 patients, and 47% had caseloads of more than 100 patients. In a recent study by Bogatz, Colasanto, and Sweeney (2005), nephrology social workers reported that large caseloads hindered their ability to provide clinical interventions. Social work respondents in this study reported caseloads as high as 170 patients and 72% of had a median caseload of 125 patients. The researchers found that 68% of social workers did not have enough time to do casework or counseling, tasks mandated by the current conditions of coverage, 62% did not have enough time to do patient education, and 36% said that they spent excessive time doing clerical, insurance, and billing tasks. One participant in their study stated: 'the combination of a more complex caseload and greater number of patients to cover make it impossible to adhere to the federal guidelines as written. I believe our patients

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May 4, 2005

Via Overnight Courier

Center for Medicaid and Medicare Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Ave., S.W.
Washington, D.C. 20201

Re: **File Code: CMS-3818-P**
Comments to Proposed Conditions of Coverage

Dear Secretary Leavitt and Administrator McClellan:

DaVita writes to comment on the proposed *Medicare Program: Proposed Conditions for Coverage for End Stage Renal Disease Facilities*, 70 Fed. Reg. 6184 (Feb. 4, 2005). We would like to make several general comments first and then comment in detail on a number of the proposed Conditions.

DaVita is pleased that the proposed conditions increase the focus on patients and emphasize teamwork. DaVita's core values are aligned with your goals of improving patient care, facilitating teamwork, and adopting the principles of continuous improvement.

While the proposed Conditions seek to achieve these goals, they contain three formidable negative themes. These themes will adversely affect individual dialysis facilities and the dialysis community in general if not tempered in the Final Rule. They are:

- A strong attempt to micromanage process;
- Unfunded mandates and a tremendous disconnect between the proposed Conditions of Coverage and the current inadequate payment policy, particularly apparent in the role of the Registered Nurse; and
- Assumption of responsibilities by CMS and Medicare that properly rest with individual states or physicians.

With respect to the conflict between the proposed Conditions and the current payment system, the challenges facing dialysis providers have never been more clearly defined. In its January 2005 report, MedPAC acknowledges that dialysis facilities are suffering losses in 2005 on Medicare patients. (As a result, MedPAC recommends a 2.5% increase

to the composite rate in 2006.) There is no financial room for error by dialysis facilities treating Medicare patients.

As a result of Medicare's insufficient payments to providers, dialysis providers have become more and more efficient in their delivery of care—including making difficult choices regarding deployment of nurses, social workers, technicians, dieticians, and other health care workers. Even though providers have sought these efficiencies with increasing intensity over the last decade, the reported quality of care achieved by dialysis facilities has steadily risen.

In spite of the necessary and appropriate tradeoffs made by providers over the last decade, the proposed Conditions appear to seek to require providers to reverse the efficiencies they gained and to burden dialysis staff with responsibilities that properly should be in the purview of physicians or to micromanage how facilities deploy their resources. We caution the Secretary to avoid this approach.

Before addressing the specific sections of the proposed Conditions, we would like to comment generally on one of the consistent themes of the proposed rules. This theme relates to the role of the registered nurse in the dialysis facility.

Registered nurses are a limited resource in American healthcare. Their role should focus around the following activities:

- Patient assessment, care planning and implementation and patient teaching are core activities of the registered nurse.
- Treatment and medication administration by appropriately licensed medical professional and appropriate delegation and supervision to licensed practical nurses and unlicensed assistive personnel.
- Patient safety activities relating to oversight and supervision of care provided in the Facilities.
- Outcomes and protocol management in conjunction with the Physician.
- Participation in quality improvement and patient care meetings and troubleshooting and investigations of incidents.

Time spent on *collection* of data would seem to be not an essential function as opposed to *participating in analysis*. The above statements inherently include the obvious fact the CMS payments for dialysis services must reflect appropriate costs of registered nurse activities. The present payment structure is currently not adequate for any expansion of the registered nurse role.

Indeed, if the present payment structure remains unaltered, it is likely in the near future that given the salary requirements and shortages of nurses, that dialysis facilities will need to look at delivery of care models that function with minimal in-center nursing. This very real possibility needs to be given careful review and analysis by CMS.

Comments to Proposed Conditions of Coverage

I. Patient Safety Conditions

Infection Control— **Proposed § 494.30** (a) Standard: Oversight. The facility must— (2) Designate a *registered nurse as the* infection control or safety officer,	**Change Proposed:** **Delete:** *"registered nurse as the"* **Rationale:** A registered nurse should not be required to serve as the infection control or safety officer. While we recognize and support the importance of vigilant control of infection as a separate condition for coverage, dialysis facilities currently have policies and procedures in place that are updated as new guidelines are set forth by agencies such as the Centers of Disease Control and Prevention. We agree that there is the need for a designated infection control or safety officer, but this does not require a registered nurse because the information that will be documented and analyzed by the designated individual will be reported to the facility chief executive officer and to the quality improvement committee (the composition of which includes a registered nurse). Although a registered nurse is qualified and is the preferred member of the interdisciplinary team to serve in this capacity, this may place an undue burden on the registered nurses who are employed by the dialysis facility. Nurses are a scarce resource in all health care venues and this requirement may also limit registered nurse involvement in performing tasks that are solely within the scope of practice of the registered nurse.

Isolation Rooms—Proposed § 494.30(a) The facility must demonstrate that it follows standard infection control precautions by implementing— **(1)** *The "Recommended Infection Control Practices for Hemodialysis Units at a Glance[]" . . .* **(2)** Patient isolation procedures to minimize the spread of infectious agents and communicable diseases	**Change proposed:** Clarify the language of the regulation, and the preamble statements at 70 Fed. Reg. 6192, that not each and every dialysis facilities is required to adhere to that portion of the CDC "Recommended Infection Control Practices for Hemodialysis Units at a Glance" that would require an isolation room or area for patients with hepatitis B. **Rationale:** No additional requirements are necessary that would require mandatory isolation rooms for hepatitis B. The rate of hepatitis B has consistently declined and there is no evidence that our present policy is inadequate. This is an example within the proposed rules of an unfunded mandate with no corresponding positive public health impact.

Water Systems—"Compliance with Laws and Regulations"—Proposed § 494.20 The preamble states: "We propose to retain the requirement that dialysis facilities must be in compliance with applicable Federal, State, and local laws and regulations pertaining to fire safety, equipment, and any other relevant health and safety issues. We are also proposing that dialysis facilities must be in compliance with the appropriate Federal, State, and local laws and regulations regarding drug and medical device usage. An example of meeting applicable Federal regulations is that the dialysis facility must use FDA-approved/cleared medical devices and adhere to the devices' labeling instructions." 70 Fed Reg. at 6191	**Change Proposed:** **Rationale:** There is no federal regulation requiring dialysis facilities to use FDA approved/cleared medical devices. FDA-approval/clearance regulations are directed toward manufacturers or suppliers of medical devices—not users. In particular, we would like to point out that manufacturers or suppliers of water purification systems who market their product for use in hemodialysis are required to submit premarket notification (510(k)'s) as described in the FDA document "Guidance for the Content of Premarket Notifications for Water Purification Components and Systems for Hemodialysis" issued May 30, 1977. There are many water treatment systems in current use that were installed prior to issuance of the May 1997 FDA guidance document for water system regulatory submissions. These older systems may be safe, effective and fully meet the most recent ANSI/AAMI recommendations. Their replacement with 510(k)-cleared systems would incur needless expense. An assessment for compliance with ANSI/AAMI recommendations is a more meaningful measure of water purification system safety than whether the system manufacturer or supplier has obtained FDA marketing clearance. This would involve potentially replacing parts of any and all water treatment system installed before 1997. We believe that this was not your intent and represents poor language choice and thus needs to be resolved.

Water Quality—Proposed § 494.40 (a) *Standard: Water purity.* Water used for dialysis meets the following water quality standards and equipment requirements of the Association for the Advancement of Medical Instrumentation (AAMI) published in ''Water Treatment Equipment for Hemodialysis Applications,'' ANSI/AAMI RD62: 2001, which are incorporated by reference.	**Change Proposed:** The regulations should not incorporate by reference "Concentrates for Hemodialysis" ANSI/AAMI RD61:2000, "Water Treatment for Hemodialysis Applications" ANSI/AAMI RD62:2001, as stated in Subsection (a), but rather should incorporate only "Dialysate for Hemodialysis" ANSI/AAMI RD52:2004, as referenced in Subsection (a)(2)(C). **Rationale:** "Dialysate for Hemodialysis" is aimed specifically at users. Furthermore, because it is the most recent document, it contains the most up-to-date ANSI/AAMI recommendations.
Water Quality—Proposed § 494.40(2)(i) The preamble states that "Bacteria and bacterial endotoxin levels of water must be measured— ++ Where water enters the dialyzer reprocessing equipment . . . ."	**Change Proposed:** The proposal to draw bacterial and bacterial endotoxin samples where water enters reprocessing equipment should be modified to alternatively allow drawing such samples where the dialyzer is connected to the reuse system. **Rationale:** This change is inconsistent with the recommendations contained in "Reuse of Hemodialyzers" ANSI/AAMI RD47-2002/A1:2003.
Water Quality —Proposed § 494.40 The preamble states that "Bacteria and bacterial endotoxin levels of water must be measured— ++ Outlet of the water storage tanks, if used . . . ."	**Change Proposed:** The proposal to draw monthly bacterial and bacterial endotoxin samples at the outlet of water storage tanks, if used, should be withdrawn. **Rationale:** Routine, monthly testing is not needed for this sample location. Note that ANSI/AAMI RD52:2004 states that testing from this location... "may be necessary during initial qualification of a system or when troubleshooting the cause of contamination within the distribution loop."

Water Quality—Proposed § 494.40 The preamble states that "Bacteria and bacterial endotoxin levels of water must be measured— ++ Concentrate or from the bicarbonate concentrate mixing tank . . . ."	**Change Proposed:** The proposal to draw monthly bacterial and bacterial endotoxin samples from concentrate or from the bicarbonate mixing tank should be modified to be where water enters equipment used to prepare bicarbonate or water from the bicarbonate mixing tank. **Rationale:** This change is consistent with the recommendations of ANSI/AAMI RD52:2004. Note that ANSI/AAMI RD52:2004 gives the rationale in section A.4.2.2 for not routinely testing bicarbonate concentrate for bacterial or endotoxin levels.
Water Quality—Proposed § 494.40 The preamble states: "Ultrapure dialysate has received attention in the clinical literature and the working draft AAMI standards ''Dialysate for Hemodialysis'' RD52 contains guidelines pertaining to ultrapure dialysate. We are not proposing a requirement for ultrapure dialysate at this time but we do invite comment on this topic." 70 Fed. Reg. at 6195.	**Change Proposed:** We would like to respond to the invitation to comment on ultrapure dialysate. **Rationale:** In our opinion, there is increasing evidence that ultrapure dialysate offers important benefits to our patients. However, there are presently no definitive studies and there are significant technical, therapeutic and logistic questions that remain unanswered. For example, the bacterial culture methods needed to ensure the quality of ultrapure dialysate are not currently available in the typical outpatient setting. It is premature to require ultrapure dialysate. We are hopeful, however, that future developments will clearly establish its benefits and offer the means for routine, widespread use.

Water Quality—Proposed § 494.40 The Preamble states that "we are requesting comments on whether the current AAMI guidance regarding carbon tanks is adequate to address all potential health and safety problems associated with chlorine, chloramines, and unannounced variations in source water. Specifically, we seek comments regarding where there is sufficient evidence to require Medicare-participating dialysis facilities to maintain at least two carbon tanks (that is, primary and backup) as part of their water treatment system, regardless of the current composition of its source water." 70 Fed. Reg. at 6247.	**Change Proposed:** We would like to respond to the invitation to comment on whether two carbon tanks should be required regardless of source water composition. **Rationale:** We believe that, unless the source water contains a substance monitored downstream of a primary carbon tank, there is no basis for requiring a second (backup) carbon tank.

Physical Environment—Proposed § 494.60 (e) *Standard: Fire safety.* (1) The dialysis facility must meet applicable provisions of the 2000 edition of the Life Safety Code of the National Fire Protection Association (which is incorporated by reference in § 403.744(a)(1)(i) of this chapter). (2) Chapter 5 of the 2000 edition of the Life Safety Code does not apply to a dialysis facility. (3) If *CMS finds that* a State has a fire and safety code imposed by State law *that adequately protects a dialysis facility's patients, CMS may allow* the State survey agency *to* apply the State's fire and safety code instead of the Life Safety Code.	**Change Proposed:** Strike ". . . CMS finds that" and ". . . that adequately protects a dialysis facility's patients, CMS may allow . . ." from subsection §494.60(e)(3), and replace the word "to" with "shall" in the same subsection. **Rationale:** Rather than proposing an additional standard in specifications regarding fire walls and fire alarm systems it would be more appropriate for the facility to comply with respective state or local fire and building regulations. Buildings are inspected on a regular basis by State regulatory agencies both during and after construction. We support the use of Automated External Defibrillators ("AEDs") in the dialysis facility because training staff in the use of these could be accomplished with CPR training. The use of non-automated defibrillators require staff to be certified in Advanced Cardiac Life Support ("ACLS"). ACLS courses are not readily available to dialysis facilities, are time consuming, and are costly.
Defibrillators—Proposed § 494.60(c) (3) *Emergency equipment and plans.* Emergency equipment, including, but not limited to, . . . defibrillator, . . . must be on the premises at all times and immediately available.	**Change Proposed:** **Rationale:** We agree that it would be appropriate for each facility to have a defibrillator. This is a new mandate and a potentially expensive one. Therefore, we strongly recommend that **CMS pay for the defibrillators in a one-time grant.** Given the present reimbursement for a treatment by CMS which is below facility costs, such an economic burden should be born by the federal government.

Suction—Proposed § 494.60(c) (3) *Emergency equipment and plans.* Emergency equipment, including, but not limited to, . . . suction, . . . must be on the premises at all times and immediately available.	**Change Proposed:** We recommend deleting the requirement for a suction machine. **Rationale:** This is rarely used and is costly to maintain.

II. Patient Clinical Care

Patient Assessment—Proposed § 494.80 (b) Standard: Frequency of assessment for new patients. (1) An initial comprehensive reassessment *must be conducted within 20* calendar days after *first dialysis treatment.*	**Changes Proposed:** **Replace:** "*must be conducted within 20*" with "should be completed within 30 days" **Clarify:** "*first dialysis treatment*" refers to the first treatment in the outpatient dialysis facility. **Rationale:** The Preamble requests comments from the community regarding the timing of the Patient Assessment. Patients who are new to dialysis may be unstable and are often subject to hospitalization during their first 90 days of dialysis. Also, members of the interdisciplinary team may be part-time employees who are not in the facility every day. Finally, a patient may begin dialysis somewhere other than the dialysis facility that ultimately will be his or her regular clinic. Thus, the proposed conditions of coverage should specify that a ***target*** date for completion of the comprehensive patient assessment of 30 days from the first dialysis treatment in the outpatient dialysis facility. DaVita's current policy is to require the assessment to be completed within 30 days of a patient's first appearance at one of our facilities. An even better method would be to target the assessment to occur after 13 *consecutive* treatments in the dialysis facility.

Patient Assessment—Proposed § 494.80(a) The proposed subsection lists specific elements that must be contained in the Patient Assessment.	**Change Proposed:** Delete §494.80(a)(1)—(13) or modify subsection (a) to generally state the requirements of a Patient Assessment.
	Rationale: We question the need for CMS to list components of the assessment criteria, consistent with CMS's stated goal to eliminate unnecessary requirements The interdisciplinary team will be able to develop an appropriate assessment tool. The exact form of that tool should not be mandated.
Plan of Care—Proposed §§ 494.90 The Preamble states that "[i]n proposed § 494.90 we would specify that the patient's plan of care must include measurable and expected outcomes and estimated timetables to meet the patient's medical and psychosocial needs as identified in the initial and subsequent comprehensive assessments." 70 Fed. Reg. at 6205.	**Change Proposed:** The Secretary should clarify this section to make clear that the dialysis facility is not responsible for setting or meeting timetables for meeting patients' medical and psychosocial needs.
	Rationale: The proposal to have "estimated timetables to meet patient's medical and psychosocial needs as identified..." is an example of micromanagement that provides no added value to patient care. This should be determined by the number of co-morbidities as well as the patient's social, economic and psychological support structures. No clinical matrix exists in the literature that would allow for definitive response times to be calculated given the large number of situations that exist now and are possible in the future.

Patient Plan of Care—Proposed § 494.90 (a) Standard: Development of patient plan of care. (6) Rehabilitation status. The interdisciplinary team *must provide the necessary care and services* for the patient to achieve and sustain an appropriate level of productive activity, including vocational, as desired by patient, including the educational needs of pediatric patients.	**Change Proposed:** **Clarify or delete:** "*must provide the necessary care and service*". **Rationale:** We question the need for CMS to list components of the patient plan of care, consistent with CMS's stated goal in the Introduction section of the Preamble to eliminate unnecessary requirements. The interdisciplinary team, if meeting the personnel qualifications as defined in the proposed regulations and who participate in the quality assessment and performance improvement program, will be able to develop the plan of care that should not be mandated, but would include measurable and expected patient outcomes to conform to current evidence-based community-accepted standards. We recognize the importance of rehabilitation, the ultimate goal of renal rehabilitation and the need for the interdisciplinary team to inform and education the patient about the value of rehabilitation. The preamble states that the responsibility of the facility and the interdisciplinary team is to refer patients to appropriate agencies and health professionals for additional services that the facility cannot provide. The actual language of the condition suggests, however, that the facility is held accountable for providing this directly. We recommend CMS change the language to reflect what CMS intended in the preamble.

Patient Communication Regarding Suitability for Transplantation or Home Dialysis— **Proposed § 494.80(a)(1):** The patient's comprehensive assessment must include, but is not limited to, the following: . . . . (10) Evaluation of suitability for a transplantation referral, based on criteria developed by the prospective transplantation center and its surgeon(s). If the patient is not suitable for transplantation referral, the basis for nonreferral must be documented in the patient's medical record. **Proposed § 494.90(a)(5)** (5) *Transplantation status.* When the patient is a transplantation referral candidate, the interdisciplinary team must develop plans for pursuing transplantation. The patient's plan of care must include documentation of the— (i) Plan for transplantation, if the patient accepts to transplantation referral; (ii) Patient's decision, if the patient is a transplantation referral candidate but	**Change Proposed:** This language requiring such extensive involvement by dialysis facilities and their personnel in the decisions concerning transplantation should be stricken or significantly rewritten to emphasize that the ultimate responsibility for educating patients, for subsequent referral, and for follow up on referrals, rests with physicians, in consultation with their patients. **Rationale:** The responsibility for informing patients of their suitability for transplantation and or home dialysis is that of the physician, not the dialysis provider. We have no objection to providing information to the patient on these modalities, but the decision to proceed with one or the other should be that of the physician and patient alone, and the Secretary inappropriately places that responsibility with the dialysis facility in these proposed Conditions. Dialysis facility personnel do not have the education and training to make decisions regarding transplantation or to counsel how to make them. Likewise, tracking correspondence from the transplant unit to the patient and physician needs to necessarily be between these parties. Any such condition should be based on the study and endorsement of the American College of Physicians or other physician organizations. With respect to maintaining exclusion criteria developed by the transplant center and having the facility apply these to individual patients, this is beyond the reasonable scope of practice and knowledge base of usual dialysis staff with the exception of experienced RNs. Also many facilities have patients transplanted at several different Centers. Each transplant center uses different criteria for inclusion or exclusion of a patient on the transplant waiting list. Thus, the team would have multiple challenges to work

declines the transplantation referral; or (iii) Reason(s) for the patient's nonreferral as a transplantation candidate as documented in accordance with § 494.80(a)(10) of this part **Proposed § 494.90(c)** c) *Standard: Transplantation referral tracking.* The interdisciplinary team must track the results of each kidney transplant center referral and must monitor the status of any facility patients who are on the transplant wait list. The team must communicate with the transplant center regarding patient transplant status at least quarterly or more frequently if necessary.	through when it refers to more than one transplant center. Coordinating this in a large facility will require near full time personnel who will be taking away a function of the physician and or his or her staff. The transplantation rate in the United States and any concern about it should not use the Conditions of Coverage as a vehicle of solution. Finally, here, as in other places within the draft Conditions, the Secretary incorrectly assumes that dialysis facilities can or should direct Physician behavior and prescribing decisions.

Condition: Care at Home—Proposed § 494.100	**Change Proposed:** We believe the section concerning Care at Home should include a requirement that a home dialysis provider should either own an in-center facility within a minimum of 35-50 miles of the homecare patient site of service, or, alternatively, have a written arrangement with a designated backup in-center service provider, including the on-call availability of a nurse. **Rationale:** This would permit a homecare patient to more readily be admitted to an in-center program in the case of equipment failure or other emergency.
Alternative Sanctions—Proposed § 488.606 (a) *Basis for application of alternative sanctions.* CMS may, as an alternative to termination of Medicare coverage, impose one of the sanctions specified in paragraph (b) of this section if CMS finds that— (1) *The supplier fails to participate in the activities and pursue the goals of the ESRD network that is designated to encompass the supplier's geographic area . . .*	**Change Proposed:** This subsection should be deleted entirely. **Rationale**: There necessarily needs to be clarification of "goals for ESRD Networks." Who defines these and how are they validated and communicated to Facilities? What are the checks and balances on Network behavior? How do facilities legitimately demur to requests from Networks that are overly burdensome or repetitive?

III. Administration Conditions

Condition: Personnel Qualifications—Proposed § 494.140 (e) Standard: Patient care dialysis technicians. Patient care dialysis technicians. (3) Have completed *at least 3 months experience, following* a training program that is approved by the medical director and governing body. This experience must be under the *direct* supervision of a registered nurse, and be focused on …	**Change Proposed:** **Delete:** "*at least 3 months experience, following*" and "*direct*" **Rationale.** CMS should not mandate the minimum length of the training program. The availability of training materials to all dialysis providers and improvements to the training process may allow for patient care technicians to be trained and working independently sooner than 3 months. At DaVita, we use several methods for evaluating the patient care technician as he/she completes the steps in the training program and demonstrates the skills required for providing a safe and effective dialysis treatment. These tools also assist our clinical education teams to determine whether additional training time is required. We acknowledge the comments in the preamble regarding CMS's concern to ensure that care is provided by qualified and trained patient care technicians who meet certain basic qualifications and are able to demonstrate the necessary competencies to perform the assigned duties of their positions. While the preamble references the past and current efforts by states to regulate dialysis technicians, we believe that CMS did not address an important aspect of the scope of practice of the licensed nurse. According to State nurse practice acts, rules, and ESRD-specific regulations, the licensed nurse—usually the registered nurse—must perform patient assessments, develop/implement a plan of care, and execute the treatment and medication orders prescribed by appropriately licensed medical staff (as defined by each State). These rules and regulations also state whether the licensed nurse may delegate certain tasks to other licensed (such as practical nurses) or unlicensed personnel (such as patient care technicians) within the generally accepted principles of delegation.

	It is therefore our opinion that the registered nurse, unless State rules and regulations specify otherwise (such as in the case of a practical nurse), is responsible for the nursing care that is given to patients under his/her care, whether or not the registered nurse is in direct supervision of the individual to whom the task is delegated. Therefore we believe it is appropriate for the registered nurse to delegate the experience of the training the patient care technician to another, using generally accepted principles of delegation: right task, right circumstance, right person, right direction/communication, and right supervision). It would be more reasonable to have a focused Preceptor program such as DaVita has as an alternative. Thus requiring an organized Preceptor program with periodic evaluations seems more appropriate.
Medical Directors—Proposed § 494.140(a) (a) *Standard: Medical director.* (l) The medical director must be a physician who has completed a board approved training program in nephrology and has at least 12 months of experience providing care to patients receiving dialysis.	**Change Proposed:** We request clarification in the Preamble that the language that medical directors must have "12 months experience providing care to patients receiving dialysis" should be interpreted to include clinical care experience in fellowship training.
	Rationale: We approve of the language in the proposed Conditions of the Medical Director dealing with "problem Nephrologists," but suggest that there be some reasonable basis for protection from lawsuits for the Medical Director related to this activity.

Core Performance Measures and VISION—Proposed § 494.180	**Change Proposed:** 1. Delay mandatory electronic participation in the CPM until VISION is operational. 2. Delete the provision of the proposed Rule, see, e.g., 70 Fed. Reg. at 6231 and 6241, that would require larger dialysis organizations ("LDOs") to subsidize smaller organizations by charging LDOs for VISION and giving it for free to smaller organizations.
	Rationale: The proposal for full participation in the CPM is a reasonable goal. However this cannot be implemented until the VISION and project is operational. This project has been consistently delayed and we have concerns regarding the universal applicability of VISION to all dialysis organizations. With respect to the proposed subsidy by LDOs, while we support the CPM and its expansion, including the need for the data to be transmitted electronically, these benefits are not so great as to offset the burden that would be imposed on LDOs if CMS required them to subsidize other providers. Dialysis reimbursement is not currently adequate. CMS should either pay for the improvements needed to implement VISION or press for appropriate reimbursement changes that would make it cost-effective for all dialysis organizations—large and small—to incur themselves the expense of implementing it.

Condition: Governance—Proposed § 494.180 (b) Standard: Adequate number of qualified and trained staff... (1) An adequate number of qualified personnel are present whenever patients are undergoing dialysis so that the patient/staff ratio is appropriate to the level of dialysis care given and meets the needs of patients; (2) A *registered* nurse is present in the facility at all times that patients are being treated"	**Change Proposed:** **Replace:** "*registered*" with "licensed" **Rationale:** CMS should not mandate the presence of a registered nurse at all times that patients are being treated because the Boards of Nursing in each State set forth in their nurse practice acts, rules and dialysis specific regulations the scope of practice of the licensed nurse, both registered and practical. The dialysis community finds itself in the unique position of responding to the needs of our patients and their access to dialysis care without unnecessary travel. Unfortunately this means that facilities located in a rural setting may not always have access to registered nurses with experience in dialysis. With the nursing shortage limiting the availability of professional (registered) nurses, we are concentrating our efforts on preserving the registered nurse to perform those things that, by law, only he/she can perform, while maximizing the role and function of the licensed practical nurse and unlicensed assistive personnel to safely and effectively provide care for our patients.
Acuity-Based Staffing—Proposed § 494.180(b)(1) and Request for Comment, Preamble at 70 Fed. Reg. at 6229: "We are soliciting public comment on whether we should include a requirement for an acuity-based staffing plan in § 494.180(b)(1) to ensure that every dialysis facility has ''adequate staffing'' and appropriate staff-to-patient ratios to meet the needs of its patients."	**Change Proposed:** CMS should not incorporate a requirement for an acuity-based staffing plan. **Rationale:** We believe "acuity" would be difficult to define and to maintain as changes frequently occur on a patient by patient basis from treatment to treatment. We agree with the comments in the Preamble that state that the nurse responsible for nursing services should develop the staffing plan and assignments based on the parameters set forth (patients treated per shift, individual patient characteristics/needs, expertise and experience of staff, physical layout of the treatment area, available technology and support services). Such a plan is a more nursing-sensitive model, as advocated by the American Nurses Association's "Principles for Nurse Staffing." There is no compelling evidence in the outpatient dialysis setting, however, to suggest that mandated ratios will improve outcomes.

Rehabilitation Status—Proposed §§ 494.90(a)(6) (6) *Rehabilitation status.* The interdisciplinary team *must provide* the necessary care and services for the patient to achieve and sustain an appropriate level of productive activity, including vocational, as desired by the patient, including the educational needs of pediatric patients.	**Change Proposed:** Strike this section entirely. **Rationale:** Without additional funding a redefinition of dialysis facilities' fundamental roles, dialysis facilities cannot also act as comprehensive rehabilitation coordinating centers. Such a requirement will necessitate additional support to the social worker in an administrative capacity, which is also well beyond the present payment mechanism. In addition, social workers may not be educated or trained to direct rehabilitation services. Rehabilitation is a different kind of care, requiring a different expertise. Moreover, the discussion of this requirement in this proposed subsection and in the Preamble, 70 Fed. Reg. at 6207-08, is so vague that it leaves dialysis facilities dangerously exposed to the individual preferences of surveyors without well-defined clinical objectives. Indeed, the Secretary notes that there is currently no agreed measure of rehabilitation status. 70 Fed. Reg. at 6208.

Registered Dietitian—Proposed § 494.140 (c) *Standard: Dietitian.* The facility must have a dietitian who must— . . . . (3) Have a minimum of one year's professional work experience in clinical nutrition *as a registered dietitian.*	**Change Proposed:** Delete "as a registered dietitian" in order to clarify that a dietitian's one year of clinical experience may be before or after he or she receives their registration. **Rationale:** We agree with requirements for a registered dietitian. However, we disagree with minimum of one year of professional work experience in clinical nutrition as a registered dietitian. Many dietitians obtain clinical experience prior to obtaining registration status. The professional work experience conducted during internship should apply to the experience requirement. Therefore, we recommend a change to read registered dietitian with one year of clinical experience. (The proposed requirement may result in hardship in rural dialysis centers). Also, all inexperienced renal dietitians who are new to a facility should be required to participate in training conducted by an experienced renal dietitian. This is DaVita's policy and practice.

Social Worker 494.140 (d) *Standard: Social worker.* The facility must have a social worker who— (1) Holds a master's degree in social work from a school of social work accredited by the Council on Social Work Education; and (2) Meets the practice requirements for social work practice in the State in which he or she is employed. The Preamble states that *"Facility social worker services include counseling services, long-term behavioral and adaptation therapy, and grieving therapy."* 70 Fed. Reg. at 6222.	**Change Proposed:** Delete this section entirely, or, in the alternative, eliminate from the preamble the statement that "Facility social worker services include counseling services, long-term behavioral and adaptation therapy, and grieving therapy." **Rationale:** We believe the proposed requirement to provide counseling services and long-term behavioral and adaptive therapy is fraught with potential patient danger and is not reflective of the realities of the functional role of the social worker in dialysis facilities. Many social workers are not adept at providing individual therapy and the expansion of their activities into this role provides a potential minefield of potential unwanted clinical results. Social workers spend a great percentage of their time providing for the "social" requirements of patients. This can be focused on food, clothing, shelter, transportation, and financial resources (including Medicare and insurance coverage). These are major factors contributing to the well being of patients. These are clearly in the province of the social worker, and there are no other staff members who have the training or preparation to handle the complex psychosocial issues presented by our patients to assume this function.

	By contrast, the requirement for extensive "counseling activities" by the social worker is not reflective of the present capacity of the social worker. It is pertinent to note that many social workers are not trained in this capacity or would require extensive additional training. If this is indeed the intent of the Conditions, we would expect CMS to provide funding for such education. In conjunction with this CMS should adjust the composite rate upwards to allow for additional staff. With the potential for about 1,200 Social Workers in DaVita, and a conservative estimate of $15,000 per professional, the additional cost would be at least $18 million to cover the educational expenses of social workers and an additional expense to cover new employees to assist social workers. Social workers will continue, of course, to provide emotional support and crisis intervention. The proposed Conditions, if adopted, will require an extensive increase in dialysis costs, and should not be pursued without a corresponding increase in dialysis funding.

Pharmacist—Existing § 405.2136(f)(1)(vi) and Preamble at 70 Fed. Reg. at 6224: "We invite comments regarding what role, if any, the pharmacist should play within the dialysis facility as well as the facility's appropriate responsibility for pharmaceutical services and the efficient use of medications in the new conditions for coverage."	**Change Proposed:** There should be no requirement that dialysis facilities have a pharmacist—either part time or full time—on their staff. **Rationale:** Such a requirement is unnecessary and would be unduly burdensome, with no material corresponding benefit. Under the present reimbursement formula, which does not cover the current cost of providing treatments and pharmaceuticals to dialysis patients, it is unrealistic to discuss the addition of a pharmacist to the team. The nephrologist has expertise in dosing and interactions of drugs commonly used in ESRD. Moreover, the dialysis facility lacks the expertise to manage a licensed pharmacist. The average salary of a pharmacist is $73,000 as outlined by the APA. Given 1,200 units, this would necessitate an increase in the composite rate of $876 million on a full time basis. Even if the required pharmacists would be only part-time, the resulting cost would be staggering. This is another example of an unrealistic relationship between the proposed condition and payment policy.

IV. Additional Comments

In addition to the comments above to specific questions, there are several general comments that we would like to make:

- The present CMS hematocrit measurement audit policy, which relates specifically to the provision of Erythropeoeitin (EPO) to dialysis patients, may preclude all patients from reaching an Hematocrit > 33, as proposed in the draft Conditions. We request that the Secretary specifically address in its Final Rule the interplay between these proposed Conditions of Coverage and any anemia-related coverage, payment, or audit policy established by CMS or the Secretary. We see no evidence that the authors of the proposed Conditions are mindful of CMS's and various fiscal intermediaries' policies and practices

regarding EPO, and how they may affect the laudable outcomes standard stated in the proposed Conditions.

- The Patient satisfaction survey (CAHPS) is not operational and should not be employed until the pilot is reviewed and it is extensively revised. DaVita and others have commented extensively on the risks and shortcomings of the early drafts of the CAHPS and we look forward to the data developed through the piloting currently undertaken by CMS with respect to these surveys.

- At the present time, CMS is preparing for a demonstration project to evaluate issues related and feasibility of an expanded outpatient dialysis bundle into the facility composite rate. We wish to comment that much more and detailed information is required before this issue can be approached and that discussion or reference to this is inappropriate at this time. The drivers behind laboratory and pharmaceutical utilization need to be understood in greater detail. More importantly, a consensus on what constitutes ideal ESRD therapy, in all its manifestations, needs to be achieved.

Once again, DaVita wishes to commend you on these proposed Conditions and looks forward to presenting our comments and proposals in person. We wish to emphasize, however, that new mandates for expansions of services can not be instituted without a change in the present rate of reimbursement. We encourage you to consider the matters presented in depth.

Sincerely,

DAVITA INC.

By: Charles P. McAllister
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